IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

State of Missouri; State of Utah; State of North Dakota; State of South Dakota; State of Iowa; State of Idaho; State of Arkansas; and **American College of Pediatricians**, *Plaintiffs*, v. **Xavier Becerra**, in his official capacity as Secretary of the United States Department of Health and Human Services; **United States Department of Health and Human Services**; **Melanie Fontes Rainer**, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services; **Office for Civil Rights of the United States Department of Health and Human Services**; **Chiquita Brooks-LaSure** in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; **Centers for Medicare and Medicaid Services**, *Defendants*.	**Case No. _____**

COMPLAINT

INTRODUCTION

1. Doctors should not be compelled to harm children. But a new final rule from the U.S. Department of Health and Human Services (HHS) under Section 1557 of the Affordable Care Act forces doctors to perform, refer for, or affirm harmful gender-transition procedures *and* forces States to pay for these dangerous procedures in state health plans. HHS, Final Rule, *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024) ("the 1557 rule" or "the rule"). This radical mandate will hurt children.

2. HHS threatens to punish doctors and States who do not comply with the mandate by imposing huge financial penalties and excluding them from federally funded healthcare programs like Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This punishment would effectively preclude doctors and States from providing healthcare for the most vulnerable children in low-income communities.

3. This harmful rule violates the Affordable Care Act (ACA), the Administrative Procedure Act (APA), the structural principles of federalism, and the freedom of speech.

4. Congress did not authorize any of this. The rule purports to implement the sex-discrimination prohibition in Section 1557 of the ACA, but there is no gender-transition mandate in that statute, nor in Title IX of the Education Amendments of 1972 from which it is derived. Nor did the rule (or the ACA) satisfy the constitutional requirements of clear notice for such a mandate: the States and healthcare providers did not agree to provide, pay for, or affirm gender-transition procedures when they began Medicaid, Medicare, and CHIP.

5. Plaintiffs State of Missouri, State of Utah, State of Arkansas, State of Iowa, State of North Dakota, State of South Dakota, and State of Idaho, and the

American College of Pediatricians thus seek judicial relief to shield patients and doctors from HHS's illegal and harmful rule.

6. This is not the first time HHS has distorted Section 1557's meaning. In fact, courts have thrice struck down similar HHS efforts to force healthcare providers and health plans to provide or pay for these dangerous, life-altering procedures. HHS in 2016 promulgated a similar rule that attempted to expand Section 1557's protections against sex discrimination to include "gender identity." A federal district court enjoined that attempt, noting that such a reading "conflict[ed] with Title IX, [Section 1557's] incorporated statute." *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941–45 (N.D. Tex. 2019). A few years later, a federal district court enjoined HHS's similar 2021 guidance, finding HHS's conclusion that "denial of … care solely on the basis of a patient's sex assigned at birth or gender identity likely violates Section 1557" to be "arbitrary and capricious." *Texas v. EEOC*, 633 F. Supp. 3d 824, 838, 847 (N.D. Tex. 2022). The same court held likewise for HHS's similar 2021 "notification" of this position on Section 1557. *Neese v. Becerra*, 640 F. Supp. 3d 668, 675–78 (N.D. Tex. 2022).

7. HHS is unwilling to let multiple adverse judgments stand in the way of ideology. Plaintiffs now ask this Court to hold HHS's *fourth* attempt to impose this mandate similarly unlawful, as at least three courts have already suggested. *See* Order, *Tennessee v. Becerra*, No. 1:24cv161-LG-BWR, 2024 WL 3283887, *13 (S.D. Miss. July 3, 2024); Mem. Op., *Texas v. Becerra*, No. 6:24-cv-00211-JDK, *2, (E.D. Tex. July 3, 2024); Order, *Florida v. U.S. Dep't of Health & Human Servs.*, No. 8:24-cv-1080-WFJ-TGW, *1–2 (M.D. Fla. July 3, 2024). This Court should delay and enjoin the rule preliminarily and permanently, declare it to be unlawful, and set it aside.

JURISDICTION AND VENUE

8. This case seeks declaratory, injunctive, and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02; the Administrative Procedure Act (APA), 5 U.S.C. § 701–06; and Federal Rule of Civil Procedure 57.

9. This Court has the authority to grant Plaintiff States the relief they request under the APA, 5 U.S.C. §§ 705–06; the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02; the Constitution; and the Court's inherent equitable powers.

10. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and federal law.

11. This Court has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

12. This Court has jurisdiction under 28 U.S.C. § 1361 to compel an officer of the United States or any federal agency to perform his or her duty.

13. This Court has inherent jurisdiction to review and enjoin *ultra vires* or unconstitutional agency action under an equitable cause of action. *See Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

14. The APA provides jurisdiction and a cause of action to review Defendants' actions and enter appropriate relief. 5 U.S.C. §§ 553, 701–06.

15. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a).

16. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412.

17. Venue is proper in this Court and this division under 28 U.S.C. § 1391, including paragraph (e).

18. Defendants are agencies of the United States, and officers and employees of the United States or of any agency thereof acting in their official capacity or under color of legal authority.

19. Plaintiff State of Missouri resides in the Eastern Division of the Eastern District of Missouri. Missouri is a resident of every judicial district and division within its sovereign territory, including this judicial district and division. *See, e.g.*, *Texas v. Garland*, 2023 WL 4851893, at *3 (N.D. Tex. July 28, 2023) (noting that a "state resides at every point within its boundaries") (brackets accepted) (quoting *Atlanta & F.R. Co. v. W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892)); *see also Florida v. United States*, No. 3:21-cv-1066, 2022 WL 2431443, at *2 (N.D. Fla. Jan. 18, 2022) ("It is well established that a state 'resides at every point within its boundaries.'" (brackets accepted) (quoting *Atlanta & F.R. Co.*, 50 F. at 791)); *California v. Azar*, 911 F.3d 558, 569–70 (9th Cir. 2018) ("[A] state with multiple judicial districts 'resides' in every district within its borders."); *Utah v. Walsh*, No. 2:23-CV-016-Z, 2023 WL 2663256, at *3 (N.D. Tex. Mar. 28, 2023) ("Texas resides everywhere in Texas."); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005) ("[C]ommon sense dictates that a state resides throughout its sovereign borders.").

20. The Eastern Division of the Eastern District of Missouri is a proper division for this action because a substantial part of the events giving rise to this action occurred in this division, the Missouri Attorney General maintains a physical office in this division, and no Defendant resides in the State of Missouri.

21. A substantial part of the events or omissions giving rise to the claims occurred in this district, because the case concerns the impact of Defendants' regulation on the State of Missouri and its operations in this division of this district. For example, located in this district are many healthcare facilities subject to the rule, both state facilities, such as the St. Louis Forensic Treatment Center and Hawthorn Children's Psychiatric Hospital, as well as several private facilities, such as the Washington University Medical Campus, Barnes-Jewish Hospital, and SSM Health Saint Louis University Hospital.

22. The rule purposely regulates medical providers and health insurance plans across the country, including those located in the Plaintiff States. Therefore, this Court has personal jurisdiction over the HHS Secretary, its Director of the Office for Civil Rights (OCR), and the Administrator of the Centers for Medicare & Medicaid Services (CMS), for purposes of this action because their immunity has been abrogated by 5 U.S.C. § 702, and they have "submit[ted]" to such jurisdiction "through contact with and" regulatory "activity directed at" Plaintiff States and their respective medical providers and health plans. *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 881 (2011).

PARTIES

Plaintiff State of Missouri

23. Plaintiff State of Missouri is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. "[F]rom time immemorial," the States have maintained primary responsibility for regulating the medical field through their constitutionally reserved powers to protect their citizens' health and welfare. *Dent v. West Virginia*, 129 U.S. 114, 122 (1889).

24. Missouri has the sovereign authority to promulgate standards of care for licensed physicians and to determine what medical procedures are reasonable for purposes of Medicaid coverage.

25. Missouri, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the rule. 42 U.S.C. § 18116(a). That includes Missouri Medicaid and Children's Health Insurance Program ("CHIP") programs.

26. As of February 2024, a total of 1,355,155 Missourians are enrolled in Medicaid and CHIP, of which 1,260,376 Missourians are enrolled in Medicaid and 94,779 Missourians are enrolled in CHIP. Missouri's total child enrollment in Medicaid Child and CHIP includes 666,697 Missouri children.[1]

27. Missouri Medicaid spending is historically 37.5% percent of the state's total budget (for comparison, total state spending on elementary and secondary education is 21.3% of the total state budget and total state spending on higher education is 4.3% of the total state budget).[2] Missouri historically spends about $13.44 billion on Medicaid each year with the help of $10.563 billion in annual federal funding.[3] Missouri historically spends about $366.3 million on CHIP each year with the help of $294.1 million in annual federal funding.[4]

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[1] HHS, CMS, *State Medicaid and CHIP Applications, Eligibility Determinations, and Enrollment Data*, https://tinyurl.com/wjcsun9z (last updated May 31, 2024) (hereinafter *CMS February 2024 Medicaid & CHIP Enrollment Data Highlights*); *see also id.* at https://tinyurl.com/5t4ndah2.

[2] Medicaid and CHIP Payment and Access Commission (MACPAC), *Exhibit 5 Medicaid as a Share of States' Total Budgets and State-Funded Budgets, SFY 2021* (Dec. 2023), https://www.macpac.gov/wp-content/uploads/2023/12/EXHIBIT-5.-Medicaid-as-a-Share-of-States-Total-Budgets-and-State-Funded-Budgets-SFY-2021.pdf (hereinafter *MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets*). The Medicaid and CHIP Payment and Access Commission (MACPAC) is a non-partisan federal legislative branch agency that provides data analysis on Medicaid and CHIP to Congress, HHS, and the States. *See* 42 U.S.C. § 1396(b)(3).

[3] MACPAC, *MACStats: Medicaid and CHIP Data Book, Exhibit 16 Medicaid Spending by State, Category, and Source of Funds, FY 2022 (millions)* (Dec. 2023), https://www.macpac.gov/wp-content/uploads/2023/12/EXHIBIT-16.-Medicaid-Spending-by-State-Category-and-Source-of-Funds-FY-2022.pdf (herein after *MACPAC Exhibit 16 Medicaid Spending by State*).

[4] MACPAC, *MACStats: Medicaid and CHIP Data Book, Exhibit 33 CHIP Spending by State, FY 2022 (millions)* (Dec. 2023), https://www.macpac.gov/wp-content/uploads/2023/12/EXHIBIT-33.-CHIP-Spending-by-State-FY-2022.pdf (hereinafter *MACPAC Exhibit 33 CHIP Spending by State*).

28. Missouri also has medical facilities that provide hormonal treatment for minors for various physical conditions, but not for the purpose of "gender transition" or treating gender dysphoria.

29. Missouri sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens. Andrew Bailey, the Attorney General of Missouri, is authorized to "institute, in the name and on the behalf of the state, all civil suits and other proceedings at law or in equity requisite or necessary to protect the rights and interests of the state." Mo. Rev. Stat. § 27.060.

Plaintiff State of Utah

30. Plaintiff State of Utah is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Utah has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies.

31. Utah, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the rule. 42 U.S.C. § 18116(a). That includes Utah's Medicaid and CHIP programs.

32. As of February 2024, a total of 346,761 Utahns are enrolled in Medicaid and CHIP, of which 313,162 Utahns are enrolled in Medicaid and 33,599 Utahns are enrolled in CHIP. Utah's total child enrollment in Medicaid Child and CHIP includes 174,084 Utah children.[5]

[5] *CMS February 2024 Medicaid & CHIP Enrollment Data Highlights*, *supra*.

33. Medicaid spending is historically 19.8% of the state's total budget (for comparison, total state spending on elementary and secondary education is 24.2% of the total state budget and total state spending on higher education is 12.3% of the total state budget).[6] Utah historically spends about $4.398 billion on Medicaid each year with the help of $3.428 billion in annual federal funding.[7] Utah historically spends about $128.4 million on CHIP each year with the help of $104.3 million in annual federal funding.[8]

34. Utah sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens. Sean D. Reyes, the Attorney General of Utah, is authorized to sue on the State's behalf.

Plaintiff State of Arkansas

35. Plaintiff State of Arkansas is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Arkansas has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies.

36. Arkansas, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the rule. 42 U.S.C. § 18116(a). That includes Arkansas's Medicaid and CHIP programs.

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[6] *MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets*, *supra*.

[7] *MACPAC Exhibit 16 Medicaid Spending by State*, *supra*.

[8] *MACPAC Exhibit 33 CHIP Spending by State*, *supra*.

37. As of February 2024, a total of 778,355 Arkansans are enrolled in Medicaid and CHIP, of which 740,363 Arkansans are enrolled in Medicaid and 37,992 Arkansans are enrolled in CHIP. Arkansas's total child enrollment in Medicaid Child and CHIP includes 345,689 Arkansas children.[9]

38. Medicaid spending is historically 26.1% of the state's total budget (for comparison, total state spending on elementary and secondary education is 12.8% of the total state budget and total state spending on higher education is 12.2% of the total state budget).[10] Arkansas historically spends about $8.975 billion on Medicaid each year with the help of $7.311 billion in annual federal funding.[11] Arkansas historically spends about $232.1 million on CHIP each year with the help of $196.0 million in annual federal funding.[12]

39. Arkansas sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens. Tim Griffin, the Attorney General of Arkansas, is authorized to sue on the State's behalf. He is authorized to "maintain and defend the interests of the state in matters before the United States Supreme Court and all other federal courts." Ark. Code Ann. § 25-16-703(a).

Plaintiff State of Iowa

40. Plaintiff State of Iowa is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Iowa has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for

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[9] *CMS February 2024 Medicaid & CHIP Enrollment Data Highlights*, *supra*.

[10] *MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets*, *supra*.

[11] *MACPAC Exhibit 16 Medicaid Spending by State*, *supra*.

[12] *MACPAC Exhibit 33 CHIP Spending by State*, *supra*.

purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies.

41. Iowa, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the rule. 42 U.S.C. § 18116(a). That includes Iowa's Medicaid and CHIP programs.

42. As of February 2024, a total of 699,225 Iowans are enrolled in Medicaid and CHIP, of which 616,984 Iowans are enrolled in Medicaid and 82,241 Iowans are enrolled in CHIP. Iowa's total child enrollment in Medicaid Child and CHIP includes 342,082 Iowa children.[13]

43. Medicaid spending is historically 23.2% of the state's total budget (for comparison, total state spending on elementary and secondary education is 15.6% of the total state budget and total state spending on higher education is 23.1% of the total state budget).[14] Iowa historically spends about $6.777 billion on Medicaid each year with the help of $5.016 billion in annual federal funding.[15] Iowa historically spends about $171.0 million on CHIP each year with the help of $132.6 million in annual federal funding.[16]

44. Iowa sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens. Brenna Bird, the Attorney General of Iowa, is authorized to sue on the State's behalf under Iowa Code § 13.2.

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[13] *CMS February 2024 Medicaid & CHIP Enrollment Data Highlights*, *supra*.

[14] *MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets*, *supra*.

[15] *MACPAC Exhibit 16 Medicaid Spending by State*, *supra*.

[16] *MACPAC Exhibit 33 CHIP Spending by State*, *supra*.

Plaintiff State of North Dakota

45. Plaintiff State of North Dakota is a sovereign State with the authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. North Dakota, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the rule. 42 U.S.C. § 18116(a). That includes North Dakota's Medicaid and CHIP programs.

46. As of February 2024, a total of 108,629 North Dakotans are enrolled in Medicaid and CHIP, of which 105,026 North Dakotans are enrolled in Medicaid and 3,603 North Dakotans are enrolled in CHIP. North Dakota's total child enrollment in Medicaid Child and CHIP includes 52,261 North Dakotan children.[17]

47. Medicaid spending is historically 15.2% of the state's total budget (for comparison, total state spending on elementary and secondary education is 16.3% of the total state budget and total state spending on higher education is 17.0% of the total state budget).[18] North Dakota historically spends about $1.621 billion on Medicaid each year with the help of $1.143 billion in annual federal funding.[19] North Dakota historically spends about $26.7 million on CHIP each year with the help of $19.1 million in annual federal funding.[20]

48. North Dakota sues to vindicate its sovereign, quasi-sovereign, and proprietary interests. Drew Wrigley is the Attorney General of North Dakota and

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[17] *CMS February 2024 Medicaid & CHIP Enrollment Data Highlights*, *supra*.

[18] *MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets*, *supra*.

[19] *MACPAC Exhibit 16 Medicaid Spending by State*, *supra*.

[20] *MACPAC Exhibit 33 CHIP Spending by State*, *supra*.

is authorized to "[i]nstitute and prosecute all actions and proceedings in favor or for the use of the state." N.D.C.C. § 54-12-01(2).

Plaintiff States of South Dakota and Idaho

49. Plaintiff States of South Dakota and Idaho are likewise sovereign States with the authority and responsibility to protect their public fisc, as well as the health, safety, and welfare of their citizens. They also have the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by their employee health insurance policies. Through their state-level agencies and political subdivisions, these States oversee and operate "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the rule. 42 U.S.C. § 18116(a). Combined, these States receive many billions of dollars in federal funding from HHS, including funds to operate their respective Medicaid and CHIP programs. Each State sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens.

Plaintiff American College of Pediatricians (ACPeds)

50. Plaintiff American College of Pediatricians (ACPeds) is a national organization of pediatricians and other healthcare professionals.

51. ACPeds is a nonprofit organization founded in 2002 and incorporated in Tennessee with a registered agent in Tennessee.

52. ACPeds' membership includes about 400 physicians and healthcare professionals in 47 different States, including members in Arkansas, Iowa, Missouri, and Utah. Most ACPeds members are board-certified pediatricians or related specialists with active practices. ACPeds members include general pediatricians, neonatologists and other pediatric sub-specialists, pediatric

surgeons, pediatric intensivists, family-medicine physicians, and pediatricians who are dual-certified in pediatrics and internal medicine.

53. Most ACPeds members provide medical care in health programs and activities receiving federal financial assistance from HHS under Section 1557 of the Affordable Care Act (ACA), 42 U.S.C. § 18116.

54. ACPeds seeks relief for its current and future members for all aspects of their practices.

55. ACPeds and its members hold the position that gender-transition procedures are inherently dangerous. Providing, facilitating, referring for, or endorsing transition efforts violates their medical oath to "do no harm."

56. It is within ACPeds' advocacy mission to advocate and litigate for members' rights to the practice of sound medicine, which in this case is to avoid providing what the rule calls "gender-affirming care" or "gender-transition procedures."

57. The Executive Director of ACPeds is Jill Simons, MD, FCP.

58. Additional facts about ACPeds's membership are set forth in Dr. Simons' declaration (Exhibit A) and in a declaration from ACPeds member Dr. Daniel Weiss of St. George, Utah (Exhibit B).

Defendants

59. Defendant Xavier Becerra is sued in his official capacity as Secretary of the United States Department of Health and Human Services. His address is 200 Independence Avenue SW, Washington, DC 20201.

60. Secretary Becerra is responsible for the overall operations of HHS, including the Department's administration of Section 1557 and the rule. 42 U.S.C. § 18116(c).

61. Defendant United States Department of Health and Human Services (HHS) is a federal cabinet agency within the executive branch of the United States government. HHS is an agency under 5 U.S.C. §§ 551 and 701(b)(1). HHS's address is 200 Independence Avenue SW, Washington, DC 20201.

62. HHS is responsible for implementing and enforcing Section 1557 and the rule.

63. Defendant Melanie Fontes Rainer is sued in her official capacity as the Director of OCR at HHS. Her address is 200 Independence Avenue SW, Washington, DC 20201.

64. Defendant Rainer is responsible for enforcing Section 1557 and the rule.

65. Defendant the Office for Civil Rights is a division of the United States Department of Health and Human Services and is an agency under 5 U.S.C. § 551 and 701(b)(1). OCR's address is 200 Independence Avenue SW, Washington, DC 20201.

66. OCR is responsible for implementing and enforcing Section 1557 and the rule.

67. Defendant Centers for Medicare and Medicaid Services (CMS) is an agency within HHS that participated in the promulgation of the rule and will implement amendments to the CMS regulations.

68. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. She is sued in her official capacity only.

69. Collectively, Defendants are referred to as "HHS" unless indicated otherwise.

BACKGROUND

I. Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972

70. In 2010, Congress approved, and President Obama signed into law, the Patient Protection and Affordable Care Act ("ACA"). Pub. L. No. 111-148 (March 23, 2010).

71. Section 1557 of the ACA states:

> Except as otherwise provided for in this title (or an amendment made by this title), an individual *shall not, on the ground prohibited under* title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), *title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.)*, the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29 [commonly known as Section 504 of the Rehabilitation Act], *be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance*, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a) (emphasis added).

72. Section 1557 does not create any new bases of prohibited discrimination. By referencing Title IX and three other well-established federal nondiscrimination provisions, "Congress incorporated the legal standards that define discrimination under each one." *Doe v. BlueCross BlueShield of Tennessee, Inc.*, 926 F.3d 235, 239 (6th Cir. 2019).

A. Title IX of the Education Amendments of 1972

73. Section 1557 prohibits discrimination on the basis of sex to the extent such discrimination is prohibited by Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 *et seq*. (Title IX).

74. Congress passed Title IX in 1972 to promote women's equal opportunities in education.

75. Under Title IX's sex discrimination provision, "[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681(a).

76. Sex is a term that refers to whether a person is male or female according to biology.

77. This was also the ordinary public meaning of "sex" at the time of Title IX's enactment. *Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791, 817 (11th Cir. 2022) (en banc); *see also Neese v. Becerra*, 640 F. Supp. 3d 668, 683 (N.D. Tex. 2022); *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 687–88 (N.D. Tex. 2016) (*Franciscan Alliance I*); *Texas v. United States*, 201 F. Supp. 3d 810, 832–33 (N.D. Tex. 2016).

78. Sex discrimination is forbidden under Title IX, its regulations, and longstanding guidance.

79. Title IX, its regulations, and longstanding guidance require education programs to provide females, as such, with equal opportunities.

80. In many cases, such as in sports with physical contact, these opportunities must be specific to sex.

81. Title IX, its regulations, and longstanding guidance do not mention or forbid discrimination based on "gender identity."

82. Title IX consistently treats "sex" as binary. *See, e.g.*, 20 U.S.C. §§ 1681(a)(2), 1681(a)(6), 1681(a)(8), 1681(a)(9), 1681(b).

83. The original post-enactment regulations implementing Title IX, *see* C.F.R. pt. 86 (1975) (now codified at 34 C.F.R. pt. 106), likewise treat sex as binary, referring multiple times to "one sex," especially versus "the other sex"; using the

phrase "both sexes"; referencing "boys and girls" and "male and female teams"; and preserving certain sex-separated spaces. *See, e.g.*, 34 C.F.R. §§ 106.33, 106.34(a)(3), 106.36(c), 106.37(a)(3), 106.41, 106.51(a)(4), 106.58(a), 106.60(b), 106.61.

84. In the decades after Title IX's enactment, the Department of Education consistently interpreted "sex" as a biological-binary classification—male and female—consistent with the statutory text, structure, and purpose and with the statute's implementing regulations.

85. Thus, it is unsurprising that when the ACA was enacted in 2010, "no federal court or agency had interpreted Title IX sex discrimination to include gender identity." *Franciscan Alliance I*, 227 F. Supp. 3d at 688.

B. Section 1557 of the Affordable Care Act

86. The ACA does not mention gender identity.

87. The ACA refers to sex and the sexes with biologically binary language.

88. The ACA acknowledges that medical practice is biological and the ACA is tailored to advance health according to biological distinctions between the male and female sexes.

89. The ACA does not require healthcare providers to practice medicine as if males are females or vice versa.

90. The ACA cannot be construed legitimately to require entities covered by Section 1557 to provide, facilitate, or speak in favor of "gender transitions."

91. The ACA maintains the States' power to regulate the medical field, as well as providers' power to practice medicine consistent with their ethical and evidence-based obligations to patients.

92. Under a "[r]ule of construction regarding health care providers," "the development, recognition, or implementation of any guideline or other standard under any Federal health care provision"— including any provision of the ACA—

"shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim." 42 U.S.C. § 18122(1), (2)(A). Nor, the provision goes on, shall any implementation of the ACA "be construed to preempt any State or common law governing medical professional … actions or claims." *Id.* § 18122(3).

93. The ACA sets further limits on HHS's ability to promulgate regulations interfering with healthcare entities' and professionals' provision of medical care. Relevant here, a statutory section entitled "[a]ccess to therapies" states that "[n]otwithstanding any other provision" of the ACA, the agency "shall not promulgate any regulation" that, inter alia: "impede[s] timely access to health care services"; "interferes with communications regarding a full range of treatment options between the patient and the provider"; "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions"; or "violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(2)–(5).

94. 42 U.S.C. § 18116 does not authorize HHS to issue a rule implementing Section 1557 to require performing or promoting "gender transitions."

C. Section 504 of the Rehabilitation Act of 1973

95. Section 1557 specifically excludes from the scope of its disability nondiscrimination requirements under Section 504 of the Rehabilitation Act of 1973 "transsexualism" and any "gender identity disorder" "not resulting from physical impairments." 42 U.S.C. § 18116(a) (prohibiting discrimination "on the ground prohibited under … section 794 of title 29"); 29 U.S.C. § 705(20)(F)(i) (providing that "transsexualism" and "gender identity disorders not resulting from physical impairments" are not a "disability" under section 794).

96. Section 504 excludes conditions other than "gender identity disorders" from the definition of "disability." These include "transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, . . . or" a catchall category of "other sexual behavior disorders." 29 U.S.C. § 705(F)(i).

97. When Congress passed this law, gender identity disorder was understood to include what today is considered gender dysphoria, that is, distress and discomfort from identifying as a gender different from the gender assigned at birth. Those terms were synonymous with having a transgender identity, so such persons that do not have a disorder of sex development—a physical impairment—do not have a "disability" and are excluded from Section 504 of the Rehabilitation Act.

98. Having gender dysphoria, identifying as transgender, non-binary, or otherwise contrary to sex is not necessarily a physical, versus mental impairment.

99. Having gender dysphoria, identifying as transgender, non-binary, or otherwise contrary to sex falls under the exclusion for gender identity disorders or the catchall exclusion category.

100. Individuals experiencing stress and discomfort about their gender incongruity do not have a physical impairment based on the fact that their sex is different from the gender with which they identify because it would read "not resulting from physical impairments" out of the statute.

101. Multiple federal courts have considered whether gender dysphoria could be a disability given the exclusion of "gender identity disorders not resulting from physical impairments." Many of these courts held that it could not. *See, e.g.*, *Duncan v. Jack Henry & Assocs., Inc.*, 617 F. Supp. 3d 1011, 1055–57 (W.D. Mo. 2022); *Lange v. Houston Cty.*, 608 F. Supp. 3d 1340, 1362 (M.D. Ga. 2022); *Doe v. Northrop Grumman Sys. Corp.*, 418 F. Supp. 3d 921, 930 (N.D. Ala. 2019); *Parker v. Strawser Constr. Inc.*, 307 F. Supp. 3d 744, 753–55 (S.D. Ohio 2018); *Gulley-*

Fernandez v. Wis. Dep't of Corrections, 2015 WL 7777997, at *3 (E.D. Wis. Dec. 1, 2015).

102. Section 504 moreover generally defines "disability" as "a physical or mental impairment that constitutes or results in a substantial impediment to employment." 29 U.S.C. § 705(9)(A); *see also id.* at § 705(20). Section 504 also incorporates by reference the definition found in the Americans with Disabilities Act, *see* 29 U.S.C. § 705(9)(B), which generally defines disability as "a physical or mental impairment that substantially limits one or more major life activities." 42 U.S.C. § 12102(1)(A). Incorporating language from the ADA, Section 504 states that "major life activities include, but are not limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working." 42 U.S.C. § 12102(2)(A). In addition, "a major life activity also includes the operation of a major bodily function, including but not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions." *Id.* § 12102(2)(B).

II. Having gender dysphoria, identifying as transgender, non-binary, or otherwise contrary to sex does not necessarily substantially limit a major bodily function and thus standing alone is not a disability covered under Section 504. Section 1557's breadth and scope

103. Section 1557 applies to what HHS calls "covered entities," which are recipients of federal financial assistance from HHS or through the ACA, such as Medicaid and CHIP.

104. These recipients of federal financial assistance include clinics, hospitals, and doctors that accept patients paying through Medicare, Medicaid, and CHIP, as well as certain pharmacies and health insurance issuers.

105. Section 1557 applies to virtually every healthcare entity in America.

106. An entity that "any part of which" participates in HHS financial assistance programs is subject *in all aspects* to Section 1557. All the operations of the covered entity are covered—not merely that part of the covered entity that receives the funding. That means that any hospital or doctors' office that accepts a single Medicare, Medicaid, or CHIP patient must follow Section 1557's policies for *all* its patients, no matter how other patients pay for care.

107. Through Medicare, Medicaid, and CHIP, the federal government is the single largest source of spending on healthcare—providing 33% of all U.S. health spending in 2022.[21]

108. Medicare is a federal health insurance program for people over 65 or who have certain disabilities or conditions. Medicare accounts for 21% of total health spending in the United States—over $1 out of every $5 spent.[22]

109. This year, in 2024, 98% of providers participate in Medicare.[23]

110. Medicaid is a joint federal and state health insurance program for people with limited incomes. Medicaid provides $1 out of every $6 spent nationally on healthcare. About 74.3% of all healthcare providers accept new Medicaid patients, including 84.7% of pediatricians.[24]

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[21] HHS, CMS, *National Health Expenditures 2022 Highlights* 3, https://www.cms.gov/files/document/highlights.pdf (last modified Dec. 13, 2023).

[22] HHS, CMS, *National Health Expenditures*, *supra*.

[23] HHS, CMS, *Annual Medicare Participation Announcement* 1–2, https://www.cms.gov/files/document/medicare-participation-announcement.pdf (last modified Nov. 17, 2023).

[24] MACPAC, *Physician Acceptance of New Medicaid Patients* 3–4 (June 2021), https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf.

111. Medicaid is the largest source of federal revenues for state budgets, accounting for about 45% of all state expenditures from federal funds in SFY 2021 and accounting for about 27% of total state spending for all items in state budgets.[25]

112. CHIP is a joint federal and state health insurance program for certain children who do not qualify for Medicaid. In some states, CHIP covers pregnant women. More than 88 million people, including nearly 40 million children, are enrolled in Medicaid and CHIP coverage.[26]

113. In 2023, federal spending on Medicare made up 13% of net federal outlays, and federal spending on Medicaid and CHIP made up 10% of net federal outlays.[27]

III. Section 1557's enforcement mechanisms

114. The ACA incorporates Title IX's public and private enforcement mechanisms for Section 1557 and HHS's implementing regulations. 42 U.S.C. § 18116(a).

115. If OCR finds a covered entity in noncompliance, HHS may require it to take remedial action or else lose federal funding.

116. Under this authority, OCR or the Attorney General may investigate the entity and demand the production of the entity's internal information. 18 U.S.C. § 3486; 45 C.F.R. §§ 80.6–80.11; 45 C.F.R. pt. 81; 45 C.F.R. § 92.5.

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[25] Elizabeth Williams et al., *Medicaid Financing: The Basics*, KFF, (Apr. 13, 2023), https://www.kff.org/medicaid/issue-brief/medicaid-financing-the-basics/.

[26] Press Release, HHS, *New State by State Analysis on Impact of CMS Strategies for States to Protect Children and Youth Medicaid and CHIP Enrollment* (Dec. 18, 2023), https://www.hhs.gov/about/news/2023/12/18/new-state-by-state-analysis-on-impact-cms-strategies-for-states-protect-children-youth-medicaid-chip-enrollment.html (providing state-by-state figures).

[27] Williams et al., *Medicaid Financing: The Basics*, *supra*.

117. Entities must provide this information or they arguably face criminal liability. 18 U.S.C. §§ 1516, 1518.

118. Criminal penalties also arguably apply to covered entities that receive federal funding but do not comply with Section 1557 or HHS's implementing regulations, including under federal criminal healthcare-fraud or false-claim statutes. 18 U.S.C. §§ 287, 1001, 1035, 1347; 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c).

119. Violators arguably may, and after certain criminal convictions must, be excluded by HHS from future eligibility for federal healthcare funding. 42 U.S.C. §§ 1320a-7, 1320c-5.

120. Violators of Section 1557 or HHS's implementing regulations may arguably be subject to federal civil false-claims liability, including civil penalties, treble damages, and the possibility of up to five years' imprisonment, 18 U.S.C. § 1001, and civil penalties up to $10,000 per false claim, adjusted for inflation, plus treble damages, 31 U.S.C. § 3729(a)(1) (flush language).

121. The public may file with OCR complaints about healthcare entities that they believe are not complying with Section 1557, Title IX, or HHS's implementing regulations.[28]

122. OCR will accept and investigate complaints filed under the 1557 rule.

123. Multiple courts have interpreted Section 1557 to allow members of the public to sue covered entities to require compliance.

[28] *See, e.g.*, *How to File a Civil Rights Complaint*, U.S. Dep't of Health & Human Servs., Office for Civil Rights, https://www.hhs.gov/civil-rights/filing-a-complaint/complaint-process/index.html (last visited June 28, 2024).

IV. President Biden's direction to add gender identity to Section 1557 and Title IX

124. Upon taking office, President Biden signed an executive order directing federal agencies to interpret Section 1557 and Title IX to prohibit gender-identity discrimination and to mandate the provision of many harmful gender-transition procedures.[29]

125. President Biden described state laws protecting children from harmful gender-transition procedures as laws that "defy our American values of liberty and dignity, corrode our democracy, and threaten basic personal safety."[30]

126. Since then, federal agencies have been implementing a whole-of-government agenda to redefine "sex" discrimination to prohibit gender-identity discrimination.

127. Secretary Becerra described disagreements with this gender-identity position as "the hateful and harmful beliefs of a narrow-minded few."[31] For

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[29] Exec. Order No. 13,988, Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 Fed. Reg. 7023 (Jan. 20, 2021); Exec. Order No. 14021, Guaranteeing an Educational Environment Free From Discrimination on the Basis of Sex, Including Sexual Orientation or Gender Identity, 86 Fed. Reg. 13,803 (Mar. 8, 2021).

[30] Exec. Order No. 14,075, Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, 87 Fed. Reg. 37,189 § 1 ¶ 1 (June 21, 2022) (once again directing that HHS shall "protect LGBTQI+ individuals' access to medically necessary care from harmful State and local laws and practices," "consider how to use the Department's authorities to strengthen non-discrimination protections on the basis of sex, including sexual orientation, gender identity, and sex characteristics, in its programs and services," and shall "promote expanded access to comprehensive health care for LGBTQI+ individuals, including by working with States on expanding access to gender-affirming care").

[31] Press Release, HHS, *Statements by HHS Secretary Xavier Becerra and HHS Principals on Pride Month* (June 1, 2023), https://www.hhs.gov/about/news/2023/06/01/statements-by-hhs-secretary-xavier-becerra-hhs-principals-pride-month.html.

example, he called the State of Missouri's child-protection efforts "egregious" and "unconscionable,"[32] and he described other states' child-protection efforts in similar terms.[33]

128. On May 6, 2024, HHS issued a new rule implementing Section 1557 of the Affordable Care to require the performance of and payment for life-altering gender-transition procedures. 89 Fed. Reg. 37,522.

129. The rule, in prohibiting discrimination on the basis of "gender identity" is part of these government-wide efforts by the White House. The 1557 rule was issued at the President's direction. It creates a regime requiring providers to perform—and health insurers to pay for—gender-transition procedures.

130. Secretary Becerra called the rule "a giant step forward."[34] He testified to Congress that the rule's requirements to provide gender-transition procedures must implemented by every health care entity or else they will lose federal funding. "If a health care facility is violating the law and not providing the service they're

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[32] Press Release, HHS, *Statement from HHS Secretary Xavier Becerra on Missouri's Emergency Regulation Restricting Access to Gender-Affirming Care* (April 25, 2023), https://www.hhs.gov/about/news/2023/04/25/statement-hhs-secretary-xavier-becerra-missouris-emergency-regulation-restricting-access-gender-affirming-care.html.

[33] Press Release, HHS, *Statement by HHS Secretary Xavier Becerra Reaffirming HHS Support and Protection for LGBTQI+ Children and Youth* (Mar. 2, 2022), https://www.hhs.gov/about/news/2022/03/02/statement-hhs-secretary-xavier-becerra-reaffirming-hhs-support-and-protection-for-lgbtqi-children-and-youth.html.

[34] Press Release, HHS, *HHS Issues New Rule to Strengthen Nondiscrimination Protections and Advance Civil Rights in Health Care* (Apr. 26, 2024), https://www.hhs.gov/about/news/2024/04/26/hhs-issues-new-rule-strengthen-nondiscrimination-protections-advance-civil-rights-health-care.html.

required to, they are not entitled to the resources," even if the entities object to gender-transition procedures.[35]

131. Secretary Becerra underscored that the rule seeks to preempt state child-protection laws. He said, "HHS works every day to build an America where LGBTQI+ Americans…can go to the doctor without fear of stigma or discrimination. Where the state you live in doesn't determine whether you can access lifesaving, gender-affirming care."[36]

132. In the same statement, OCR Director Melanie Fontes Rainer agreed that state child-protection laws were "hateful" and "devasting [sic]," and she called them the motivation for her work.[37]

133. The rule is thus "very clear about equal treatment under the law and how we expect it to be enforced," Director Fontes Rainer explained in an interview. "I'd be lying to you if I didn't say that there weren't laws all across the country now that are in conflict."[38]

134. Shortly thereafter, President Biden again described opposing state laws protecting children from transition procedures as part of his "top priority" and

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[35] Testimony of Xavier Becerra, House Committee on Education & the Workforce, Committee Hearing "Examining The Policies And Priorities Of The Department Of Health And Human Services" at 1:59:50 – 2:05:05. (May 15, 2024), https://edworkforce.house.gov/calendar/eventsingle.aspx?EventID=410541 & https://www.youtube.com/watch?v=TlMqoOE0YQ0.

[36] Press Release, HHS, Statements by HHS Secretary Xavier Becerra and HHS Principals on Pride Month (June 3, 2024), https://www.hhs.gov/about/news/2024/06/03/statements-hhs-secretary-xavier-becerra-hhs-principals-pride-month.html.

[37] *Id.*

[38] Ian Lopez, *Transgender Health Rule Lawsuits Piling Up Against Biden HHS*, Bloomberg News (June 20, 2024), https://news.bloomberglaw.com/health-law-and-business/transgender-health-rule-lawsuits-piling-up-against-biden-hhs.

called these child-protection laws "dangerous and hateful," with "excruciating" effects. He explained, "That is why I have taken historic action to protect the LGBTQI+ community…against discrimination when accessing health care."[39]

V. The rule's new gender-identity definitional provisions

135. The rule requires that covered entities "provide individuals equal access to [their] health programs and activities without discriminating on the basis of sex." 89 Fed. Reg. at 37,770; *see* 89 Fed. Reg. at 37694 (to be codified at 45 C.F.R. § 92.4) (defining covered entities).

136. Under the rule, "[d]iscrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity," as well as "marital, parental, or family status," and it also includes discrimination against an individual on the basis of the sex "of the individual and another person with whom the individual has a relationship or association." 89 Fed. Reg. at 37,698–99, 37,701 (to be codified at 45 C.F.R. §§ 92.101(a)(2), 92.208, 92.209).

137. The rule treats these bases of liability as overlapping ways in which Section 1557 and Title IX address gender identity.

138. For example, the rule directly defines "gender-identity" discrimination to be sex discrimination, but the rule separately defines "sex stereotypes" discrimination to be sex discrimination, and the rule considers "sex stereotypes" discrimination to encompass gender-identity discrimination. 89 Fed. Reg. at 37,699.

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[39] Proclamation No. 10,767, Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Pride Month, 2024, 89 Fed. Reg. 48,225, 48,225–26 (May 31, 2024).

139. Likewise, Section 1557 addresses disability discrimination under Section 504 of the Rehabilitation Act, but the rule references regulations that deem gender dysphoria a "disability" that can trigger the same gender-identity mandate.

140. The rule provides for discriminatory-intent liability, disparate-impact liability, hostile-environment liability, harassment liability, and other theories of liability on all these bases.

141. Consequently, to the extent this Complaint refers to, or asks the Court to issue relief concerning, the rule and Defendants' actions thereunder prohibiting discrimination on the basis of gender identity, Plaintiffs intend to encompass any language or alternative theory in the rule that Defendants may use to achieve those same ends.

142. HHS's failure to settle on a single source of authority for its gender-identity mandate highlights that the rule's stated sources of authority are pretexts to for the President and Defendants to usurp the role of Congress, to avoid the limits on HHS's enforcement powers, and to promote HHS's own policy goals of imposing a sweeping gender-identity mandate on healthcare.

VI. The rule's new gender-identity mandates

143. OCR insists using the rule to consider covered healthcare entities unlawfully not to have complied with Section 1557 and not to have provided "equal access" to health programs "without discriminating on the basis of sex" or disability unless the providers do not exclude, deny benefits, or "discriminate" against individuals on the basis of gender identity. 89 Fed. Reg. at 37,698–701 (to be codified at 45 C.F.R. §§ 92.101(a), 92.206(a), 92.208–98.211).

144. The rule requires that covered entities provide equal access without discriminating on the basis of sex, meaning gender identity.

145. The rule specifically considers it discriminatory to deny or limit health services, including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded.

146. The rule specifically considers it discriminatory to deny or limit, on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded, a health care professional's ability to provide health services if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity.

147. The rule considers it discriminatory to adopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity. (The rule says that merely "experiencing … distress" is enough to cross that de minimis threshold. *Id.* at 37,593.)

148. The rule specifically considers it discriminatory to deny or limit health services sought for the purpose of "gender transition" or other "gender-affirming care" that the covered entity would provide to an individual for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

149. By "gender-affirming care" HHS means care for "transgender" individuals (including those who identify using other terms, for example, "nonbinary" or "gender nonconforming") that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designed to support gender-transition efforts. 89 Fed. Reg. at 37,596.

150. This rule has no age limit—meaning it applies equally to minors.

A. Forcing doctors to perform "gender-transition" procedures

151. The rule forces healthcare entities to perform so-called "gender-transition" procedures.

152. "Gender-transition" procedures are drugs or interventions that block a person's natural development as a person of one sex, such as puberty-blocking drugs, cross-sex hormones, and body-altering surgeries. Many of those drugs or interventions are irreversible.

153. The rule considers it discrimination if a covered entity provides a particular health service but will not provide that health service for gender transitions or to affirm gender transitions.

154. Under the rule, healthcare providers must provide or refer for gender-transition procedures unless they have a reason that HHS considers legitimate and nondiscriminatory for denying or limiting the requested service, including where the covered entity typically declines to provide the health service to any individual, or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual. 89 Fed. Reg. at 37,698–701 (codified at 45 C.F.R. § 92.206(c)). But a covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. *Id.*

155. The rule thus would not require a doctor to provide "a prostate exam for a transgender man who does not anatomically have a prostate." *Id.* at 37,607. But categorical refusals to perform transition procedures are prohibited. *See id.* at 37,575, 37,595–97.

156. If a healthcare entity is willing to prescribe puberty blockers for therapeutic reasons related to early onset of puberty, the rule requires such an

entity to also prescribe those puberty blockers when requested by a patient to help achieve or continue a "gender transition."

157. If a healthcare entity is willing to perform a mastectomy for therapeutic reasons, such as those related to cancer, the rule requires such an entity to also perform mastectomies on women and girls to help achieve or continue a "gender transition."

158. If a healthcare entity is willing to perform a hysterectomy on a woman with a cancerous uterus, the rule requires it to perform a hysterectomy on a woman with a healthy uterus if she identifies as a man and seeks the procedure for "gender-transition" purposes.

159. Under the rule, a healthcare entity's position that services or procedures for "gender transition" are categorically never beneficial for individuals is not a sufficient basis for declining to provide that service, if it is a service they will provide when it does not have the purpose or effect of causing, assisting, or affirming "gender transition."

160. By requiring healthcare entities to provide health services that have the purpose or effect of causing, assisting, or affirming "gender transition," the rule creates a new government-mandated standard of care.

161. It is no defense to liability under the rule that in a healthcare entity's medical judgment, removing a healthy organ for "gender-transition" purposes is never clinically indicated or beneficial.

162. It is no defense to liability under the rule that a healthcare entity considers "gender-transition" efforts categorically experimental or cosmetic.

163. Covered entities must comply with the rule even if doing so violates state law, medical ethics, or the entity's own policies.

164. Under the rule, if a doctor declines to provide a procedure for "gender transition" to a minor because doing so is prohibited by state law, that reason will not protect the doctor from liability for violating the rule.

B. Forcing healthcare entities to change their speech to conform to HHS's gender ideology

165. The rules forces healthcare entities to affirm gender-transition procedures in speech and in writing.

166. The rule considers it discrimination for a covered entity to speak to patients in a way that categorically excludes the legitimacy of "gender transition."

167. The rule considers it to create a hostile environment for patients in violation of the rule if a healthcare entity and its staff speak in ways that categorically deny the medical legitimacy of gender transitions.

168. Under the rule, covered entities cannot tell their patients that in their best medical opinions, transition efforts or procedures are categorically experimental and dangerous.

169. Under the rule, covered entities cannot speak or act toward their patients on the view that transition efforts or procedures are categorically harmful.

170. Under the rule, covered entities may not raise categorical objections about transition efforts or procedures based on detransitioners' regret over these efforts.

171. Under the rule, covered entities may not raise categorical objections about "gender-transition" efforts based on their view of the harms of puberty-blocking drugs, cross-sex hormones, surgeries, and other procedures.

172. The rule forces covered entities to give patients the impression that "gender-transition" efforts can in some cases be clinically indicated or beneficial.

173. The rule forces covered entities to use self-selected pronouns contrary to sex according to biology. 89 Fed. Reg. at 37596, 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206).

174. The rule considers it discrimination for a covered entity to speak using a patient's pronouns that align with his or her sex according to the patient's biology if the patient prefers different pronouns that correspond to his or her gender identity.

175. Under the rule, if a patient identifies with a gender different from his or her sex, covered entities must refer to that patient by pronouns the patient prefers corresponding to that patient's perceived gender and not by pronouns corresponding to that patient's sex.

176. Under the rule, if a patient identifies with a gender different from his or her sex, covered entities may not omit the use of pronouns concerning that patient based on the doctor's disagreement with using biologically inaccurate pronouns.

177. Under the rule, covered entities must tell patients that males can get pregnant, give birth, and breastfeed.

178. Under the rule, covered entities must not tell patients that males categorically cannot get pregnant, give birth, and breastfeed.

179. As HHS explains in the proposal, doctors are responsible for "discrimination, stigma, and erasure" if they speak or act in way that treats "pregnancy and childbirth as something exclusively experienced by . . . women." HHS, Proposed Rule, *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824, 47,865 (Aug. 4, 2022) (NPRM).

180. Under the rule, if covered entities provide patients with written materials stating any of the things the rule considers prohibited, that would violate the rule and could also constitute discrimination.

181. Not only is speech directly regulated, HHS's enforcement decisions are also informed by "consideration of … whether [a] covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care." 89 Fed. Reg. at 37,598. Any provider who deviates from HHS's "standards of care" risks being found insufficiently willing to provide "accurate information." NPRM, 87 Fed. Reg. at 47,784. All of this seeks to give patients a false sense of certainty about the efficacy of transition procedures.

C. Putting males into female private spaces

182. The rule forces females to share private spaces with males when the male identifies as female or non-binary. NPRM, 87 Fed. Reg. at 47,866–67.

183. The rule's mandates extend to the use of sex-separated "intimate space[s]." 89 Fed. Reg. at 37,593.

184. When a male identifies as female or non-binary, covered entities must designate males to female private spaces or programs, such as sex-specific dual-occupancy hospital rooms, exam rooms, shared showers, lactation rooms, lactation training, and restrooms.

185. Under the rule, a hospital that assigns patients to intimate spaces based on sex would be forced to allow a man who identifies as a woman to share a space with a woman who identifies as a woman.

186. The hospital would not be allowed to assign rooms or chaperones on the basis of sex according to biology.

187. Under the rule, healthcare providers will not be able to honor patient requests for a healthcare provider or chaperone of a particular sex in cases where a provider, chaperone, or patient identifies contrary to his or her sex.

188. Because the rule requires covered entities to allow access to sex-specific programs or facilities according to a person's asserted gender identity, the rule forbids sex-specific programs or facilities based on biology.

D. Requiring health plans to pay for "gender-transition" procedures

189. The rule requires that covered health plans pay for gender-transition procedures. 89 Fed. Reg. at 37,701, 37,703 (to be codified at 45 C.F.R. §§ 92.207, 147.104, 155.120, 155.220, 156.200, 156.1230).

190. This includes taxpayer-funded and state-operated plans, such as state Medicaid programs, Children's Health Insurance Programs, and health plans for state employees, as well as covered plans on the group and individual health insurance markets and on ACA exchanges.

191. In doing so, the rule purports to outlaw as impermissible "sex discrimination" the choice by policymakers in Missouri, Utah, and other States to exclude insurance coverage for gender-transition procedures. 89 Fed. Reg. at 37,535.

192. The rule considers categorical exclusions of coverage for gender-transition procedures unlawful sex discrimination in providing or administering health insurance coverage or other health-related coverage.

193. Facially neutral plans with a disparate impact on gender-transition procedures are also allegedly "discriminatory" because "transgender individuals are the only individuals who seek transition-related care." NPRM, 87 Fed. Reg. at 47,871.

194. The rule considers it discriminatory to discriminate on the basis of sex, disability, or any combination thereof, defined to include gender identity.

195. The rule considers it discriminatory to deny, cancel, limit, or refuse to issue or renew health insurance coverage or other health-related coverage, or deny

or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of sex, disability, or any combination thereof.

196. The rule considers it discriminatory to have or implement marketing practices or benefit designs that discriminate on the basis of sex, age, disability, or any combination thereof.

197. The rule considers it discriminatory to deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded.

198. The rule considers it discriminatory to have or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care.

199. The rule considers it discriminatory to otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction results in discrimination on the basis of sex.

200. Under the rule, health plans must pay for gender-transition procedures unless they have a reason that HHS considers legitimate and nondiscriminatory for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements. 89 Fed. Reg. at 37,701. But a covered entity's coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination. *Id.*

201. If a healthcare entity is willing to provide coverage for puberty blockers for therapeutic reasons related to early onset of puberty, the rule requires such an entity to provide coverage for those puberty blockers when requested by a patient to help achieve or continue a "gender transition."

202. If a healthcare entity is willing is willing to provide coverage for a mastectomy for therapeutic reasons, such as those related to cancer, the rule requires such an entity to provide coverage for mastectomies on women and girls to help achieve or continue a "gender transition."

203. If a healthcare entity is willing to provide coverage for a hysterectomy on a woman with a cancerous uterus, the rule requires it to provide coverage for a hysterectomy on a woman with a healthy uterus if she identifies as a man and seeks the procedure for "gender-transition" purposes.

204. Under the rule, denying "hormone therapy coverage" to a transgender person of color for a gender transition is, alone, evidence of "pervasive" "transphobia and racism." NPRM, 87 Fed. Reg. at 47,870.

205. Under the rule, a healthcare entity's position that services or procedures for "gender transition" are categorically never beneficial for individuals is not a sufficient basis for declining to provide that coverage for "gender transitions," if it is a service the entity will cover when it does not have the purpose or effect of causing, assisting, or affirming "gender transition."

206. It is no defense to liability under the rule that in a healthcare entity's medical judgment, removing a healthy organ for "gender-transition" purposes is never medically necessary or beneficial.

207. It is no defense to liability under the rule that a healthcare entity considers "gender-transition" efforts categorically experimental or cosmetic.

208. HHS has already determined that "gender transition" is medically necessary, and that disagreeing with HHS is a pretext for discriminating. Merely

referring to transition procedures as "experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical care." NPRM, 87 Fed. Reg. at 47,874.

209. Covered entities must comply with the rule even if doing so violates state law, medical ethics, or the entity's own policies.

210. Under the rule, if health plan declines to cover a procedure for "gender transition" because doing so is prohibited by state law, that reason will not protect the health plan from liability for violating the rule.

211. HHS lists several insurance providers whose current limitations on coverage presumably violate this provision. NPRM, 87 Fed. Reg. at 47,871 n.460.

E. Requiring policies, certifications, and assurances

212. The rule requires healthcare entities to agree to comply with the rule, submit assurances or certifications of compliance, adopt policies ensuring compliance by and within the entity, notify patients of compliance, and train staff to comply. 89 Fed. Reg. at 37,693, 37,696–701 (to be codified at 45 C.F.R. §§ 92.1(b), 92.5, 92.8, 92.9, 92.10, 92.101, 92.206).

213. Under the rule, as a condition of receiving Medicare, Medicaid, or CHIP funds, each covered entity must begin to repeal existing policy, adopt new policy, make assurances to the government, give notices to patients, and train staff in order to comply with the rule's requirements to provide "gender-transition" procedures and to not speak in categorical criticism or exclusion of such procedures.

VII. The rule's overlapping gender-identity changes to CMS regulations

214. The rule makes overlapping changes to CMS regulations for Medicaid, for CHIP programs designed to provide healthcare for children and pregnant women, and for PACE's program for providing elderly care. (PACE is a Medicare and Medicaid program that helps people meet their health care needs in

the community instead of going to a nursing home or other care facility.) 89 Fed. Reg. at 37,691–92 (to be codified at 42 C.F.R. §§ 438.3, 438.206, 440.262, 457.495, 460.98, 460.112).

215. These provisions seek to have a similar effect as the provisions above in terms of requiring coverage for gender-transition procedures.

216. These provisions appear to require that States ensure that persons can demand to be referred to by pronouns that do not align with their sex.

217. They apply to States, Medicaid and CHIP managed care plans, managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, primary care case managers, and primary care case management entities in managed care programs, among others.

218. Under CMS's revised Medicaid and CHIP regulations, contracts with entities that deliver services must now include a promise that the entities will not discriminate against individuals on the basis of gender identity and will not use any policy or practice that has the effect of discriminating on the basis of gender identity. 89 Fed. Reg. at 37,691 (to be codified at 42 C.F.R. § 438.2).

219. The rule requires that Medicaid and CHIP managed care organizations "promote the delivery of services in a culturally competent manner to all enrollees … regardless of sex which includes … gender identity." 89 Fed. Reg. at 37,691 (to be codified at 42 C.F.R. § 438.206(c)(2)).

220. States and entities that deliver Medicaid or CHIP services must "promote the delivery of services in a culturally competent manner to all enrollees, … and regardless of sex which includes … gender identity." *Id.* (to be codified at 42 C.F.R. §§ 440.262 (Medicaid), 457.495(e)).

221. With respect to its PACE regulations, CMS likewise revised the regulatory language's reference to "sex" discrimination to include "gender identity." 89 Fed. Reg. at 37,669 (to be codified at 42 C.F.R. §§ 460.98(b)(3).

460.112(a)). Section 460.98 regulates services provided by State PACE programs, while § 460.112 establishes the rights of PACE participants.

222. CMS promulgated these provisions under both Section 1557 and provisions of the Social Security Act ("SSA") and the Public Health Act ("PHA"). In addition to relying on its authority under Section 1557, CMS claimed authority to make these changes to Medicaid under Sections 1102 and 1902(a)(4) of the SSA (42 U.S.C. §§ 1302, 1396a(a)(4)), to CHIP under Sections 1102 and 1902(a)(4) of the SSA (42 U.S.C. § 1302, 1396aa(a)), and to PACE under Sections 1102, 1801, 1894(f)(A) and 1934(f)(A) of the SSA (42 U.S.C. §§ 1302, 1395, 1395eee(f), 1396u-4(f)). HHS also cites the SSA's statement of purpose, Section 2101(a) of the SSA, *id*. § 1397aa.

223. The rule explains, "CMS interprets sections 1902(a)(4) and 2101(a) of the SSA [42 U.S.C. §§ 1396a(a)(4)(A), 1397aa] as authorizing CMS to adopt regulations prohibiting discrimination on the basis of gender identity or sexual orientation because such prohibitions on discrimination are necessary for the proper and efficient operation of a state plan, are in the best interest of beneficiaries, and enable states to provide child health assistance in an effective and efficient manner." NPRM, 87 Fed. Reg. at 47,892; *see also* 89 Fed. Reg. at 37,668 (similar).

224. The rule explains, "Under section 1902(a)(19) of the Social Security Act, states must provide for such safeguards as may be necessary to assure access to care and services in a manner consistent with simplicity of administration and the best interest of beneficiaries," and the rule avoids confusion, "facilitates simplicity in administration of nondiscrimination requirements and ensures the best interests of the beneficiaries are met across Medicaid delivery systems for all Medicaid beneficiaries." 89 Fed. Reg. at 37,668.

VIII. The rule's lack of a scientific basis to redefine sex to require gender-transition procedures

225. The rule lacks a scientific basis for its new mandates—in fact, HHS ignores the scientific evidence about the lack of a medical basis for gender-transition procedures.[40]

226. It is impossible to change a person's sex.

227. Sex is embedded in an individual's DNA, with women having two X chromosomes, and males having both X and Y chromosomes.

228. Medicalized transition of gender is experimental.

229. There is no evidence that gender-transition procedures improve mental health or reduce suicide or suicidality.

230. There is no reliable evidence that "social transition" (such as using pronouns contrary to a person's sex) improves minors' mental health, especially when weighed against less risky treatments.

231. Methodological defects limit or negate many such studies' evidentiary value.

232. No systematic reviews of safety and efficacy supported establishing the rule's new "standards of care," despite systematic reviews being the foundation and gold standard of evidence-based care.

233. In fact, multiple international healthcare systems that had expanded medicalized transition to include minors have reversed course based on systematic reviews concluding that the evidence on medicalized transition in minors is of poor quality.

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[40] *See, e.g.*, Declaration of James Cantor, Exh. A, *McComb Children's Clinic, Ltd. v. Becerra*, No. 5:24-cv-00048-KS-LGI (S.D. Miss. June 3, 2024); Doctors Protecting Children, *Declaration*, https://doctorsprotectingchildren.org/

234. The harms associated with administering puberty blockers or cross-sex hormones to children and adolescents include: sterilization without proven fertility preservation options, permanent loss of capacity for breastfeeding, lifetime lack of orgasm and sexual function, interference with neurodevelopment and cognitive development, substantially delayed puberty associated with medical harms, elevated risk of Parkinsonism in adult females, reduced bone density, lifetime dependence on hormone treatments, increased cardiovascular risk, and hormone-dependent cancers, among other effects.

235. Assertions that puberty blockers act only as a "fully reversible" "pause button" lack scientific evidence, and more recent evidence proves this to be false.[41]

236. But HHS seeks to impose a standard of care contrary to all of this scientific evidence—a standard of care that reflects not science but HHS's own political positions.

237. The World Professional Association for Transgender Health ("WPATH"), a prominent advocacy group, publishes what it (and HHS) describes as "standards of care" for treating people with gender dysphoria in both children and adults.[42]

238. When HHS proposed the rule, HHS decided that the relevant "professional standards of care" encompassed WPATH's "standards of care" for transition procedures. NPRM, 87 Fed. Reg. at 47,824, 47,868 (citing World Prof. Ass'n for Transgender Health (WPATH), Standards of Care for the Health of

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[41] Doctors Protecting Children, *Declaration* at ¶5, https://doctorsprotectingchildren.org/

[42] *See* WPATH, *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 Int'l J. of Transgender Health S1 (2022) ("SOC 8"); *see also* WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7* (2012), HHS-OS-2022-0012-4074 ("SOC 7").

Transsexual, Transgender, and Gender-Nonconforming People, pp. 68–71 (7th Version 2012) (SOC 7)).

239. WPATH has repeatedly warned of untested hypotheses, continuing unknowns, and lack of research.

240. Like WPATH, the Endocrine Society admits that risks associated with puberty-blocking drugs include "adverse effects on bone mineralization," "compromised fertility if the person subsequently is treated with sex hormones," and "unknown effects on brain development."[43]

241. HHS has previously described WPATH as an "advocacy group." 85 Fed. Reg. at 37,198. So has WPATH itself. *See Boe v. Marshall*, No. 2:22-cv-184-LCB, Doc. 208, at 3 (M.D. Ala. Dec. 27, 2022).

242. Additional evidence undermining WPATH's materials emerged after HHS proposed the rule, and these WPATH internal records were presented to HHS and are in the administrative record.[44]

243. Further recent disclosures confirm that WPATH's recommendations are not medical or scientific but, instead, are politically influenced.

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[43] Wyle C. Hembree, Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 10 J. Clin. Endocrinol. & Metab. 3869, 3882 (2017), https://academic.oup.com/jcem/article/102/11/3869/4157558?login=true, HHS-OS-2022-0012-4060 ("Endocrine Society Guideline").

[44] *See, e.g.*, Mia Hughes, *WPATH Files Excerpts: Exposing the Realities of Gender Medicine, Environmental Progress* (Mar. 4, 2024), https://environmentalprogress.org/s/U_WPATHExcerpts.pdf; Mia Hughes, The *WPATH Files: Pseudoscientific Surgical and Hormonal Experiments on Children, Adolescents, and Vulnerable Adults*, Environmental Progress 71 (Mar. 4, 2024), https://environmentalprogress.org/s/WPATH-Report-and-Files111.pdf; *cf.* Doctors Protecting Children, *Declaration* at ¶4, https://doctorsprotectingchildren.org/ ("There is now sufficient research to further demonstrate the failure of the WPATH, American Academy of Pediatrics and Endocrine Society protocols).

244. WPATH emails have revealed that WPATH members admit that WPATH guidelines were prepared to further advocacy and litigation against state laws restricting gender-transition procedures for minors.[45]

245. Worse, since the rule was proposed, HHS has directly politicized the most recent guidelines from WPATH.

246. WPATH emails have also revealed that during the preparation of the rule, HHS officials in the office of HHS Assistant Secretary for Health Rachel Levine successfully directed WPATH (over WPATH member objections) to remove all age limits from SOC 8, the most recent guidelines, because HHS feared any age limits could support state laws restricting gender-transition procedures for minors.[46]

247. WPATH emails show that Levine spoke to WPATH and was "very eager for [the SOC 8 guidelines'] release—so to ensure integration in the US health policies of the Biden government." Levine's office sent WPATH messages that "should be taken as a charge from the United States government to do what is required to complete the project immediately." Another email documented how "Sarah Boateng, who served as Levine's chief of staff [said the] biggest concern is the section below in the Adolescent Chapter that lists specific minimum ages for treatment, she is confident, based on the rhetoric she is hearing in DC, and from what we have already seen, that these specific listings of ages, under 18, will result

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[45] Appendix A to Supplemental Expert Report of James Cantor, Ph.D., *Boe v. Marshall*, No. 2:22-cv-00184, ECF No. 591-24 at *9–10 (M.D. Ala. June 24, 2024).

[46] A. Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. Times (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

in devastating legislation for trans care. She wonders if the specific ages can be taken out."[47]

248. Levine "was very concerned that having ages (mainly for surgery) will affect access to health care for trans youth and maybe adults too. Apparently the situation in the USA is terrible and she and the Biden administration [are] worried that having ages in the document will make matters worse. She asked us to remove them." [48] (Levine is a male who identifies as female and who has selected female pronouns. The "she" in these emails refer to Levine.)

249. WPATH emails show that WPATH complied with HHS's charge: "[W]e heard your [Dr. Levine's] comments regarding the minimal age criteria for transgender healthcare adolescents; the potential negative outcome of these minimal ages as recommendations in the US [. . .] Consequently, we have changes to the SOC 8 in this respect."[49]

250. Rather than deny these reports, HHS confirmed in an official statement that "Adm. Levine shared her view with her staff that publishing the proposed lower ages for gender transition surgeries was not supported by science or research, and could lead to an onslaught of attacks on the transgender community."[50]

251. Likewise, emails have revealed that WPATH commissioned studies from Johns Hopkins University and then attempted to stop Johns Hopkins from

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[47] Cantor Appendix, supra at *11.

[48] Cantor Appendix, supra at *11–12.

[49] Cantor Appendix, supra at *12.

[50] Roni Caryn Rabin, Teddy Rosenbluth, & Noah Weiland, *Biden Administration Opposes Surgery for Transgender Minors* (June 28, 2024), https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html.

publishing them because the studies found little to no evidence about transitions for children and adolescents.[51]

252. Countries in Europe such as Sweden, Norway, Finland, and others have determined in recent years that there is no solid evidence to support interventions on minors. Countries across Europe have thus greatly restricted those interventions for minors. For example, after a peer-reviewed, systematic review of the evidence was published in Sweden finding no solid evidence for these interventions, the Swedish health authority determined in February 2022 that "the risks of puberty treatment with GnRH-analogues [puberty blockers] and gender-affirming hormonal treatment [cross-sex hormones] currently outweigh the possible benefits."[52]

253. Finland does not provide surgical treatments for gender dysphoria in minors.[53]

254. Scotland's National Health Service has stopped all new prescriptions of puberty-blocking drugs and other hormone treatments for minors.[54]

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[51] United States Department of Health and Human Services' Response to Motions to Seal, Dkt. No. 100, *Voe v. Mansfield*, Case No. 1:23-cv-864, at *9–11 (M.D.N.C. May 13, 2024).

[52] *Care of Children and Adolescents with Gender Dysphoria: Summary*, Socialstyrelsen: The National Board of Health and Welfare 3 (Feb. 2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf

[53] Palveluvalikoima, *Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendation*, at *2, https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474

[54] BBC, *Scotland's under-18s gender clinic pauses puberty blockers*, https://www.bbc.com/news/uk-scotland-68844119 (April 18, 2024)

255. The Norwegian Healthcare Investigation Board recommends that puberty delaying treatment (puberty blockers) and hormonal and surgical gender affirmation treatment for children and adolescents be defined as an investigational treatment. This is because the evidence base, especially research-based knowledge for gender affirmative treatment (hormonal and surgical) is insufficient and the long-term effects are poorly known.[55]

256. The German Medical Assembly in 2024 asked the German government to only allow puberty blockers, sex-change hormone therapies or gender reassignment surgery to under 18-year-olds with gender incongruence (GI) or gender dysphoria (GD) in the framework of controlled scientific studies, involving a multidisciplinary team and a clinical ethics committee and after medical and, in particular, psychiatric diagnosis and treatment of any mental disorders. It also recommended that therapy outcomes of any interventions of this kind be followed up over a period of at least ten years. It reasoned that puberty blocking drugs, cross-sex hormone therapy, and gender reassignment surgery do not improve gender dysphoria, gender incongruence symptoms, or mental health in minors with those conditions.[56]

257. The National Health Service in Great Britain commissioned a report by Dr. Hilary Cass, who came to the following conclusions in April 2024 about "gender transitions." First, systematic evidence reviews demonstrated the poor quality of the research in this field, meaning that there is not a reliable evidence

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[55] Ukom, *Patient safety for children and young people with gender incongruence*, at *2, *4 (March 9, 2023) (Exhibit C).

[56] 128th German Medical Assembly, *Treatment of gender dysphoria in minors* (Medical Assembly Circular No. Ic-048) (2024) (Exhibit D).

base upon which to make clinical decisions.[57] Second, the rationale for early puberty suppression remains unclear, with weak evidence regarding the impact on gender dysphoria, mental or psychosocial health, and its effect on cognitive and psychosexual development remains unknown.[58] Third, the use of masculinizing/feminizing hormones in those under 18 presents many unknowns.[59] Fourth, clinicians are unable to determine with certainty which children and young people will go on to have an enduring trans identity.[60]

258. In sum, the rule is based on politics, not science. The evidence supporting transition procedures is weak at best. HHS concluded as much in 2016 and again in 2020, when it remarked on the lack of "high quality evidence" to support the efficacy of gender-transition surgeries and other treatments.[61]

IX. Plaintiff States' regulation of gender-transition procedures

259. Tracking the developing international consensus, 25 States have restricted access to gender-transition treatments for children.[62] Plaintiff States

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[57] *The Cass Review: Independent review of gender identity services for children and young people*, Final Report at *385, https://cass.independent-review.uk/wp-content/uploads/2024/04/CassReview_Final.pdf

[58] *The Cass Review: Overview of key findings*, https://cass.independent-review.uk/home/publications/final-report/

[59] *Id.*

[60] *Id.*

[61] Tamara S. Jensen, et al., Decision Memo, CAG #00446N, Centers for Medicare & Medicaid Servs. (Aug. 30, 2016), https://perma.cc/R2ME-YQRA; 85 Fed. Reg. at 37,187; *see also* Endocrine Society Guideline, *supra* (acknowledging that most of its recommendations regarding gender-transition procedures are based on "low quality" or "very low quality" evidence).

[62] *E.g.*, Ala. Code §26-26-4; Ariz. Rev. Stat. § 32-3230; 2021 Ark. Act 626 (enacting Ark. Code Ann. § §20-9-1501 through -1504); Fla. Admin. Code Ann. R.64B8-9.019; Ga. Code Ann. §31-7-3.5; Idaho Code §18-1506C; Ind. Code §25-1-22-13; Iowa Code §147.164; Ky. Rev. Stat. Ann. §311.372; La. Stat. Ann. §40:1098; Miss. Code Ann. §41-

have adopted laws prohibiting healthcare providers from offering gender-transition treatments to minors. Plaintiff States have likewise chosen not to cover certain gender-transition procedures through their Medicaid, CHIP, or state employee health programs. Private health plans in these States have hitherto been free to not to have to pay for gender-transition procedures.

260. Plaintiff States will be unable to enforce these duly enacted laws and longstanding policies without coming into conflict with the rule.

261. The States have exercised their constitutional longstanding and sovereign interests "'in protecting the integrity and ethics of the medical profession,' and 'preserving and promoting the welfare of the child'" to restrict gender-transition procedures for minors. *See, e.g.*, *L.W. ex rel. Williams v. Skrmetti*, 83 F.4th 460, 473 (6th Cir. 2023) (citations omitted) (cert. granted in related case *United States v. Skrmetti*, No. 23-5600 (6th Cir.), *see United States v. Skrmetti*, No. 23-477 (U.S.)).

262. The rule has no authority to preempt these state laws.

263. But the rule purports to sweep these state laws aside. 89 Fed. Reg. at 37,535.

A. Missouri

264. The Missouri Save Adolescents from Experimentation (SAFE) Act is a pause on these experimental gender-transition procedures, as the world awaits more data.

141-1-9; Mo. Rev. Stat. Ann. §191.1720 (§ 191.1720.3, RSMo); S.B. 99, 68th Leg., 2023 Sess. (Mont. 2023); Neb. Rev. Stat. §72-7301-07; H.B. 808, 2023 Sess. (N.C. 2023); N.D. Cent. Code. §12.1-36.1-02; Ohio Saving Adolescents from Experimentation Act, 2024 Sub.H.B. No. 68; Okla. Stat. tit. 63, §2607.1; S.C. HB 4624 (2024); H.B. 1080, 98th Leg. Sess. (S.D. 2023); Tenn. Code Ann. §68-33-101; S.B. 14, 88th Leg. Sess. (Tex. 2023); Utah Code Ann. §58-68-502(1)(g); Wyo. Stat. § 35-4-1001 (effective July 1, 2024); W. Va. Code §30-3-20 (effective Jan. 1, 2024).

265. It is not every day that Missouri finds itself following the lead of the world's most progressive countries. But today Missouri sits in this unusual company because of an emerging international consensus that these procedures lack any solid evidentiary support—and because of concerns specific to Missouri.

266. In early 2023, a whistleblower provided the Attorney General's Office with a sworn affidavit and supporting documentation, raising serious allegations about the St. Louis Transgender Center at Washington University. The whistleblower, who self-identifies as queer and who is married to a person who identifies as transgender, worked at the center for years.[63] She alleged in a sworn affidavit numbering 86 paragraphs that the Center misrepresents to patients and parents the safety and efficacy of puberty blockers and cross-sex hormones, that the Center continues providing these interventions even after a parent has revoked consent, and that the Center provides life-altering hormones to children whose gender identities change day by day.[64]

267. For example, the whistleblower noted that a patient was rushed by a transgender clinic into obtaining surgery and "had their breasts removed."[65] "Three months later, the patient contacted the surgeon and asked for their breasts to be 'put back on.'"[66] As the whistleblower noted, if there "[h]ad [been] a requisite and adequate assessment been performed before the procedure, the doctors could have prevented this patient from undergoing irreversible surgical change."[67]

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[63] Affidavit of Jamie Reed (Feb. 7, 2023), https://ago.mo.gov/wp-content/uploads/2-07-2023-reed-affidavit-signed.pdf.

[64] *Id.*

[65] *Id.* ¶ 61.

[66] *Id.*

[67] *Id.*

268. One girl was placed on irreversible cross-sex hormones "only because she wanted to avoid becoming pregnant."[68] This individual needed "basic sex education," but the clinic rushed her into life-altering, chemical treatment.[69] Others have been placed on life-altering chemical treatment after coming into the clinic "using pronouns of inanimate objects like 'mushroom'" or "'rock,'" "changing their identities on a day-to-day basis," or arriving at the clinic "under clear pressure by a parent to identify in a way inconsistent with the child's actual identity."[70]

269. The whistleblower alleged that individuals from the Center lied to the legislature.[71] On April 21, 2022, two clinicians from the transgender center at Washington University testified in person before the Missouri House of Representatives and denied that any minors have received gender transition surgeries. Dr. Sarah Garwood said, "I want to underscore that at no point are surgeries on the table for anyone under the age of 18." She continued, "Surgery for trans youth is not part of anything that is recommended." Similarly, Dr. Chris Lewis, speaking just after Garwood, said: "Again, surgeries are not an option for anyone below the age of 18 years of age."

270. Washington University has since released documents confirming that these statements by its employees were false. Following the whistleblower allegations, the university launched a self-review. While Lewis and Garwood categorically denied that surgeries are ever "on the table" for minors, Washington University conceded that individuals at the university have performed transgender

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[68] *Id.* ¶ 60.

[69] *Id.*

[70] *Id.* ¶ 59.

[71] *Id.* ¶ 25.

surgeries six times in recent years and referred minors for surgery as recently as 2018.[72] And even after Washington University stopped technical "referrals," the transgender center continued providing patients with the names and phone numbers of recommended surgeons.[73]

271. One week after the whistleblower went public with her concerns, the Missouri Senate conducted a hearing over this issue.[74] The legislature ultimately enacted SB49, the Missouri SAFE Act.

272. ***Prohibition on harmful procedures on children.*** The Missouri SAFE Act restricts gender transition procedures on minors. § 191.1720, RSMo.

273. The Missouri SAFE Act prohibits health care providers from knowingly performing "a gender transition surgery on any individual under eighteen years of age." § 191.1720.3, RSMo.

274. The Missouri SAFE Act also requires health care providers not to "knowingly prescribe or administer cross-sex hormones or puberty-blocking drugs for the purpose of a gender transition for any individual under eighteen years of age," but this provision does not apply with respect to any individual who received "such hormones or drugs prior to August 28, 2023, for the purpose of assisting the individual with a gender transition," and this provision "expire[s] on August 28, 2027." § 191.1720.4, RSMo.

275. As for enforcement, the Missouri SAFE Act authorizes the licensing board to revoke a medical license, and it permits individuals to bring private causes

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[72] Washington University Transgender Center Internal Review, Summary of Conclusions (April 21, 2023), https://source.wustl.edu/wp-content/uploads/2023/04/Washington-University- Summary-of-Conclusions.pdf.

[73] *Id.*

[74] https://senate.mo.gov/23info/BTS_Web/Actions.aspx?SessionType=R&BillID=44407.

of action for damages. § 191.1720.5–6, RSMo. Nothing in the Missouri SAFE Act regulates individuals seeking these procedures.

276. The Missouri SAFE Act also makes clear that it does not apply to the rare individuals who have "disorders of sex development" (such as chromosomal abnormalities), does not apply to treatments to resolve complications caused by gender transition procedures, and does not apply when an individual's life would be in danger "or impairment of a major bodily function" would occur absent the intervention. § 191.1720.8, RSMo. Nothing in the Missouri SAFE Act prevents health care providers from engaging in well-established treatments such as counseling.

277. ***Restrictions on paying for transition procedures.*** The Missouri SAFE Act restricts state funds from paying for transition procedures for anyone of any age through state Medicaid and CHIP programs. "There shall be no payments made…for gender transition surgeries, cross-sex hormones, or puberty-blocking drugs…for the purpose of a gender transition." § 208.152.15, RSMo. MO HealthNet is the name of the state's Medicaid and CHIP program, and the agency charged with administration of the MO HealthNet is the MO HealthNet Division, a division within the Missouri Department of Social Services. § 208.001.2, RSMo.[75]

[75] *See also* Missouri Department of Social Services, History of MO HealthNet, https://mydss.mo.gov/mhd/history; Missouri Department of Social Services, Family MO HealthNet (MAGI) Manual, https://dssmanuals.mo.gov/family-mo-healthnet-magi/1840-000-00/#:~:text=CHIP%20children%20receive%20full%2C%20comprehensive,as%20well%20as%20prescription%20coverage.

278. As a matter of policy, MO HealthNet likewise has long excluded surgical transition procedures from state Medicaid and CHIP coverage for patients of any age.[76]

279. The Missouri SAFE Act prohibits the Department of Corrections from providing gender-transition surgeries to prisoners of any age, § 217.230, RSMo, and ensured that county jails need not provide gender transition surgeries to prisoners of any age, § 221.120.1, RSMo.

280. Private Missouri health plans are likewise free not to pay for transition procedures.

B. Utah

281. ***Prohibition on harmful procedures on children.*** In early 2023, Utah enacted S.B. 16, Transgender Medical Treatments and Procedures Amendments.

282. Utah's law defines as "unprofessional conduct" a healthcare provider "performing, or causing to be performed, upon an individual who is less than 18 years old" either "a primary sex characteristic surgical procedure" or "a secondary sex characteristic surgical procedure." Utah Code. Ann. §§ 58-67-502(1)(g), 58-68-502(1)(g).

283. Under Utah's law, "A health care provider may not provide a hormonal transgender treatment to a patient" who is a minor and who was "not diagnosed with gender dysphoria before the effective date" of the law. Utah Code Ann. § 58-1-603.1. Under the law, a "hormonal transgender treatment" includes cross-sex hormones and puberty-blockers. Utah Code Ann. § 58-1-603(e)(i). The term does not include medically necessary as a treatment for precocious puberty,

[76] MO HealthNet, *Physician Manual* 58–59 (Sept. 1, 2023), https://mydss.mo.gov/media/pdf/physicians-provider-manual.

endometriosis, a menstrual, ovarian, or uterine disorder, a sex-hormone stimulated cancer, or a disorder of sexual development. Utah Code Ann. § 58-1-603(e)(ii).

284. To consider whether to amend these provisions, the law also requires the state Department of Health and Human Services to conduct a systematic review of the medical evidence regarding "hormonal transgender treatments to minors." S.B. 16, § 1 (to be codified at Utah Code Ann. § 26B-1-214).

285. Utah's law also requires the Division of Professional Licensing to create a certification for providing hormonal transition procedures and requires a health care provider to meet these certification requirements before providing hormonal transition procedures to a minor. Utah Code Ann. § 58-1-603(2). In addition, a health care provider may provide cross-sex hormones or puberty blockers "to a minor only if the health care provider has been treating the minor for gender dysphoria for at least six months," has screened the minor for other physical or mental conditions, has considered alternatives, and has provided detailed information to support informed consent. Utah Code Ann. § 58-1-603(3).

286. As for enforcement, Utah's law authorizes the licensing board to discipline providers, and it permits individuals to bring private causes of action for damages. Utah Code Ann. §§ 58-1-603(j), 78B-3-427. Nothing in Utah's law regulates individuals seeking these procedures.

287. ***Protection of Sex-Based Private Facilities.*** In 2024, Utah enacted H.B. 257, Sex-Based Designations for Privacy, Anti-Bullying, And Women's Opportunities. This law protects sex-based distinctions in certain publicly owned or controlled circumstances, such as in government changing rooms or restrooms. Utah Code Ann. § 63G-31-302.

288. ***Restrictions on paying for transition procedures.***

289. In accord with S.B.16, Utah "Medicaid coverage policy has been updated to align with and prohibit certain gender dysphoria treatments for patients who are less than 18 years of age"[77] For minors, Utah Medicaid does not cover "Puberty Blocker Therapy (Gonadotropin Releasing Hormone (GnRH))," "Gender Dysphoria Hormone Therapy (cross-sex hormonal transgender treatment)," or "Sex characteristic surgical procedures for the purpose of effectuating a sex change."[78] The policy makes exceptions parallel to the scope of S.B. 16, and the policy requires prior authorization forms as well as proof that providers have a transgender treatment certification.[79]

290. Utah provides health coverage for state employees and retirees through the Utah Public Employees Health Program (PEHP). The PEHP Health & Benefits is a division of the State of Utah's Utah Retirement Systems.[80]

291. PEHP does not cover gender-transition surgeries for anyone of any age in the State Employee Health Plan: PEHP lists as a policy exclusion "Gender reassignment surgery."[81]

292. PEHP has provided a formal estimate of the cost of adding some coverage to the legislature for a fiscal note on a proposed bill that would add this

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[77] Utah Dep't of Health & Human Servs., *Medicaid Information Bulletin* (Feb. 2023), https://medicaid.utah.gov/Documents/manuals/pdfs/Medicaid%20Information%20Bulletins/Traditional%20Medicaid%20Program/2023/Special%20Interim%20MIB/February2023Interim-MIB.pdf.

[78] *Id.*

[79] *Id.*

[80] PEHP, About Us, https://www.pehp.org/about.

[81] PEHP, Provider Basics, https://www.pehp.org/mango/pdf/pehp/pdc/providerbasics_23_FE9B73F9.pdf

coverage.[82] For adding coverage for adults only, the anticipated fiscal impact is $471,829 or .12% increase in premium for Fiscal Year 2025.[83]

293. But PEHP warns that it "would expect some variance given the potential range of costs and number of surgeries that may be involved for a particular individual. Some individuals may undergo a single surgery for as little as a total cost of $10,000. Others may undergo multiple surgeries at total cost that could potentially exceed $100,000. Total costs may also increase over time as teens and young adults who identify as transgender at higher rates reach adulthood and become eligible for the benefit."[84]

294. Utah health plans are free under state law to choose not to pay for transition procedures.

C. Arkansas

295. Responding to growing international concern over the explosion in experimental gender-transition procedures performed on minors, Arkansas enacted the Save Adolescents from Experimentation ("SAFE") Act. *See* 2021 Ark. Act 626 (enacting Ark. Code Ann. §§ 20-9-1501 through -1504). The Act's legislative findings highlighted the lack of evidence about gender-transition procedures' safety, stressed those procedures' irreversible, life-long consequences for children, and concluded that "[t]he risks of gender transition procedures far outweigh any benefit at this stage of clinical study." *Id.*, sec. 2(6)-(8), (15).

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[82] PEHP, HJR 2, Joint Resolution For Gender Reassignment Surgical Benefits, (Hayes, S) https://www.urs.org/documents/byfilename/@Public%20Web%20Documents@URS@External@FiscalNotes@PEHP@2024@HJR2@@application@pdf/.

[83] *Id.*

[84] *Id.*

296. ***Prohibition on harmful procedures on children.*** The SAFE Act therefore prohibited practitioners from providing or referring for transition procedures on children or referring children for transition procedures. Ark. Code Ann. § 20-9-1502. The Act defines "gender transition procedures" as "any medical or surgical service . . . including . . . puberty-blocking drugs, cross-sex hormones, . . . or genital or nongenital gender reassignment surgery performed for the purpose of assisting an individual with a gender transition." Ark. Code Ann. § 20-9-1501(6)(A). It does not prohibit any gender-transition procedure for adults. *See id.* § 20-9-1502(a). And it does not prohibit—indeed, it encourages—providing children mental health services to address their psychological distress. *See* SAFE Act, 2021 Ark. Act 626, sec. 2(4). Nothing in the Arkansas SAFE Act regulates individuals seeking these procedures.

297. As for enforcement, the Arkansas SAFE Act authorizes the licensing board to revoke a medical license, and it permits individuals to bring private causes of action for damages. Ark. Code Ann. § 20-9-1504.

298. Arkansas's Protecting Minors from Medical Malpractice Act of 2023 likewise creates civil liability for providers who perform transition procedures on minors, Ark. Code Ann. § 16-114-402, and preserves freedom of conscience and medical judgment so that healthcare professionals do not to have to perform transition procedures on anyone, Ark. Code Ann. § 17-80-122.

299. ***Restrictions on paying for transition procedures.*** The Arkansas SAFE Act includes a prohibition on the direct or indirect use of public funds for gender-transition procedures for an individual under eighteen (18) years of age. Ark. Code Ann. § 20-9-1503(a). The Act prohibits providing transition procedures to minors in any state, county, or local government healthcare facility and prohibits any state, county, or local government healthcare professional employees from furnishing transition procedures to minors. Ark. Code Ann. § 20-9-1503(b). The Act

requires that the Arkansas Medicaid Program "not reimburse or provide coverage for gender transition procedures to an individual under eighteen (18) years of age." Ark. Code Ann. § 20-9-1503(d).

300. The Arkansas SAFE Act states that insurers shall not pay for transition procedures for minors and need not pay for them for anyone of any age. Under the Act, a "health benefit plan under an insurance policy or other plan providing healthcare coverage in this state *shall not include* reimbursement for gender transition procedures for a person under eighteen (18) years of age" and that a "health benefit plan under an insurance policy or other plan providing healthcare coverage in this state *is not required* to provide coverage for gender transition procedures" for anyone. Ark. Code Ann. § 23-79-164 (emphasis added).

301. The Employee Benefits Division (EBD) of the Arkansas Department of Transformation and Shared Services (TSS) manages the group health insurance plan ARBenefits, which is available to State and public school employees, families and retirees.[85]

302. ARBenefits excludes from all coverage "Sex changes/sex therapy. Care, services, or treatment for non-congenital transsexualism, gender dysphoria, or sexual reassignment or change are not covered. This exclusion is specific to sex change/sex therapy such as medications, implants, hormone therapy, surgery, medical, or psychiatric treatment or other treatment of sexual dysfunction including Prescription Medications and sex therapy."[86]

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[85] State of Arkansas, Arkansas Department of Transformation and Shared Services, Employee Benefits, About Us, https://www.transform.ar.gov/employee-benefits/about-us/.

[86] *See, e.g.*, ARBenefits, *Plan Document For Arkansas State And Public School Employees And Retirees* at 97, https://www.transform.ar.gov/wp-content/uploads/ARBenefits-2023-Plan-Document-FINAL-6.13.23.pdf (Jan. 1, 2023).

D. Iowa

303. ***Prohibition on harmful procedures on children.*** In 2023, Iowa enacted Senate File 538, An Act Relating to Prohibited Activities Regarding Gender Transition Procedures Relative to Minors, and including Effective Date and Applicability Provisions.

304. Under Iowa's law, a health care professional shall not prescribe or administer puberty blockers, cross-sex hormones, or surgeries for the purpose of attempting to alter the appearance of, or affirm the minor's perception of, the minor's gender or sex, if that appearance or perception is inconsistent with the minor's sex." Iowa Code Ann. § 147.164(2)(a). Nor may a health care professional aid or abet providing these procedures. Iowa Code Ann. § 147.164(2)(b). The law excludes services for disorders of sexual development. Iowa Code. Ann. § 147.164(2)(c).

305. As for enforcement, Iowa's law authorizes the licensing board to provide discipline for unprofessional conduct, the attorney general to bring an action to enforce the law, and individuals to bring private causes of action for damages. Iowa Code Ann. §§ 147.164(2)(d), 147.164(3).

306. ***Restrictions on paying for transition procedures.***

307. In accord with Iowa's law prohibiting transition procedures for minors, Iowa Medicaid will not cover claims for prohibited transition procedures on minors.[87]

308. Private Iowa health plans are likewise free not to pay for transition procedures for minors.

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[87] Iowa HHS, Iowa Medicaid, Implementation of Senate File (SF) 538-Gender Transition Procedures Relative to Minors, IL 2517-MC-FFS (Sept. 18, 2023), https://secureapp.dhs.state.ia.us/IMPA/Information/Bulletins.aspx.

E. North Dakota

309. ***Prohibition on harmful procedures on children.*** In 2023, North Dakota enacted H.B. 1254 to protect minors from life-altering gender modification procedures. Under North Dakota law, health care providers may not perform a variety of surgical procedures "for the purpose of changing or affirming the minor's perception of the minor's sex," including castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, vaginoplasty, or mastectomy. N.D.C.C. § 12.1–36.1–02(1)(a)-(b), (d). Willful violation of those provisions is punishable as a class B felony. N.D.C.C. § 12.1–36.1–02(2)(a). Nor may a healthcare provider "[p]rescribe, dispense, administer, or otherwise supply any drug that has the purpose of aligning the minor's sex with the minor's perception of the minor's sex when the perception is inconsistent with the minor's sex. N.D.C.C. § 12.1–36.1–02(1)(c). Willful violation of those provisions is punishable as a class A misdemeanor. N.D.C.C. § 12.1–36.1–02(2)(b). North Dakota's prohibitions do not apply to minor "born with a medically verifiable genetic disorder of sex development," or to procedures that began before the statute took effect. N.D.C.C. § 12.1–36.1–03.

310. ***Protection of Sex-Based Private Facilities.*** In 2023, North Dakota enacted H.B. 1473 to protect sex-segregated spaces in restrooms, locker rooms, and shower rooms in a dormitory or living facility controlled by the state board of higher education, as well as in the state penitentiary and correctional facilities. N.D.C.C. §§ 12-44.1-09.1, 12-46-26, 12-47-40, 15-10-68.

F. Other Plaintiff States

311. The other Plaintiff States have laws restricting gender-transition procedures for minors.

312. The other Plaintiff States restrict payment by the state for coverage of gender-transition procedures for minors.

313. Private health plans have been hitherto free not to pay for transition procedures in these States.

G. The rule's derogation of Plaintiff States' sovereignty

314. Each State "has a significant role to play in regulating the medical profession," *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007), as well as "an interest in protecting the integrity and ethics of the medical profession," *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). This includes "maintaining high standards of professional conduct" in the practice of medicine. *Barsky v. Bd. of Regents of Univ. of N.Y.*, 347 U.S. 442, 451 (1954).

315. The State also "has an interest in protecting vulnerable groups … from abuse, neglect, and mistakes," *Glucksberg*, 521 U.S. at 731, and in "the elimination of particularly gruesome or barbaric medical procedures," *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 301 (2022). It is also "evident beyond the need for elaboration that a State's interest in 'safeguarding the physical and psychological well-being of a minor' is 'compelling.'" *New York v. Ferber*, 458 U.S. 747, 756–57 (1982) (quoting *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 607 (1982)).

316. States have "sovereign interests in enforcing their duly enacted state laws." *Tennessee*, 615 F. Supp. 3d at 841.

317. Thus, "irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws." *Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) (collecting cases); *see also, e.g.*, *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J.: "[A]ny time a State is enjoined by a court from

effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.").

X. The rule's lack of authority to preempt these state laws

318. Since Congress enacted the ACA, HHS has twice tried and failed to use Section 1557's prohibition on sex-based discrimination as a mandate to provide and pay for transition procedures.

A. The Obama Administration's vacated 2016 rule

319. Well into President Obama's first term, federal regulators heeded the historical understanding of Title IX as limited to sex-based discrimination. In a 2010 "Dear Colleague Letter" on bullying, the Obama Department of Education acknowledged that Title IX did not cover claims of sex discrimination by lesbian, gay, bisexual, and transgender students based on their "LGBT status" alone.[88] Instead, the letter advised, any claims must overlap with allegations of "sexual harassment or gender-based harassment."[89]

320. Yet, a few years later, things began to shift. In 2014, the Department of Education performed an about-face by asserting that "Title IX's sex discrimination prohibition extends to claims of discrimination" based solely on "gender identity."[90]

321. In 2016, HHS followed suit with a rule that defined Section 1557's prohibition of discrimination "on the basis of sex" to include discriminating against an individual "on the basis of … gender identity." HHS, *Nondiscrimination in*

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[88] U.S. Dep't of Educ., Off. for Civ. Rts., Dear Colleague Letter on Bullying, at 8 (Oct. 26, 2010) (marked "not for reliance"), https://perma.cc/3AGM-SB8P.

[89] *Id.*

[90] U.S. Dep't of Educ., Off. for Civ. Rts., Questions and Answers on Title IX and Sexual Violence, at 5 (Apr. 29, 2014) (rescinded in 2017), https://perma.cc/Y7BD-XHFU.

Health Programs and Activities, 81 Fed. Reg. 31,375, 31,467. (May 18, 2016) ("2016 Rule"). The 2016 Rule defined "gender identity" as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." *Id*.

322. The 2016 Rule required covered entities—including "almost all licensed physicians"—to perform or refer patients for sex-transition procedures. *See* 81 Fed. Reg. 31,445. And it prohibited insurers from maintaining "explicit, categorical (or automatic) exclusion[s] or limitation[s] of coverage for all health services related to gender transition." *Id*. at 31,429.

323. The U.S. District Court for the Northern District of Texas preliminarily enjoined and later vacated HHS's rule insofar as it purported to prohibit "discrimination on the basis of gender identity." *Franciscan All.*, 227 F. Supp. 3d at 696. The court concluded that "HHS's expanded definition of sex discrimination" that included gender identity "exceed[ed] the grounds incorporated by Section 1557" because "the meaning of sex in Title IX unambiguously refers to 'the biological and anatomical differences between male and female students as determined at their birth.'" *Id*. at 687, 689 (citation omitted); *accord Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941–45 (N.D. Tex. 2019).

324. The vacatur of the 2016 Rule remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022).

B. The Biden Administration's vacated 2022 guidance

325. During President Trump's Administration, HHS issued a rule rescinding the failed 2016 Rule and that specified that "the term 'on the basis of … sex' in Section 1557 does not encompass discrimination on the basis of gender identity." HHS, *Nondiscrimination in Health and Health Education Programs or*

Activities, Delegation of Authority, 85 Fed. Reg. 37,160, 37,191 (June 19, 2020) ("2020 Rule").

326. In 2020, HHS confirmed that Section 1557 and Title IX do not prohibit discrimination on the basis of gender identity. HHS, *Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority*, 85 Fed. Reg. 37,160 (June 19, 2020) (to amend and be codified at 45 C.F.R. pt. 92). This textual interpretation protected "providers' medical judgment . . . thus helping to ensure that patients receive the high-quality and conscientious care that they deserve." 85 Fed. Reg. at 37,206. With considerable understatement, HHS noted "that the medical community is divided" on the wisdom of gender transitions. 85 Fed. Reg. at 37,187–88.

327. Again, in 2021, HHS confirmed that the "lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation."[91]

328. In May 2021, HHS published guidance purporting to interpret Section 1557 "consistent with" *Bostock v. Clayton County*, by reading the statute to prohibit "[d]iscrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." HHS, *Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972*, 86 Fed. Reg. 27,984 (May 25, 2021) ("*Bostock* Notification").

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[91] HHS, Agency for Healthcare Research and Quality (AHRQ), *Topic Brief: Treatments for Gender Dysphoria in Transgender Youth* at 1 (Jan. 8, 2021), https://effectivehealthcare.ahrq.gov/system/files/docs/topic-brief-gender-dysphoria.pdf.

329. In March 2022, HHS doubled down on this view in a second Section 1557 guidance letter.[92] This guidance reaffirmed the *Bostock* Notification's "interpretation" of Section 1557.[93] HHS further explained that efforts by covered entities to restrict access to "gender affirming care" may be treated as discrimination based on an individual's "gender identity," in violation of Section 1557.[94]

330. Then an HHS sub-agency called the Office of Population Affairs released a two-page memorandum entitled "Gender-Affirming Care and Young People."[95] In this brief document, the Office of Population Affairs asserted that "[r]esearch demonstrates that" so-called "gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents."[96] It further asserted that "[f]or transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being."[97] The two-pager prominently highlighted the treatment guidelines from the Endocrine Society and WPATH.[98] HHS threatened to sue anyone who disagreed with this purported "standard of care."[99]

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[92] U.S. Dep't of Health & Human Servs., Office for Civil Rights, HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy, (Mar. 2, 2022) ("March 2022 Guidance"), https://perma.cc/R4GJ-9CB3.

[93] *Id.* at 1–2.

[94] *Id.*

[95] *See* Office of Population Affairs, *Gender-Affirming Care and Young People*, https://perma.cc/H3CS-94KX.

[96] *Id.* at 1.

[97] *Id.*

[98] *Id.*

[99] *See* March 2022 Guidance 1–2.

331. A federal district court later vacated and set aside as unlawful the March 2022 Guidance, finding HHS's conclusion that "denial of … care solely on the basis of a patient's sex assigned at birth or gender identity likely violates Section 1557" was "arbitrary and capricious." *Texas v. EEOC*, 633 F. Supp. 3d 824, 838, 847 (N.D. Tex. Oct. 1, 2022) (brackets accepted). Among other things, the court held that the March 2022 Letter misread *Bostock* and did not adequately explain how, despite the specific exclusion of "gender identity disorders" from the definition of disability in the Rehabilitation Act (and hence in Section 1557, *see* 42 U.S.C. § 18116(a) (incorporating "section 794 of title 29")), failure to provide cross-sex hormones or gender-transition surgeries could amount to discrimination on the basis of a disability. *Id*. at 832–38. The same was true for HHS's similar 2021 "notification" of its position on Section 1557. *Neese v. Becerra*, 640 F. Supp. 3d 668, 675–78 (N.D. Tex. 2022).

332. Other federal district courts enjoined similar efforts to extend *Bostock*'s reasoning to the Title IX context. *See, e.g.*, *Tennessee v. Cardona*, No. CV 2:24-072-DCR, 2024 WL 3019146, at *9 (E.D. Ky. June 17, 2024); *Louisiana v. U.S. Dep't of Educ.*, 3:24-CV-00563, 2024 WL 2978786, at *4 (W.D. La. June 13, 2024); *Texas v. Cardona*, No. 4:23-CV-00604-O, 2024 WL 2947022, at *28–40 (N.D. Tex. June 11, 2024); *Tennessee v. Dep't of Educ.*, 615 F. Supp. 3d 807, 839 (E.D. Tenn. 2022), *aff'd*, *Tennessee v. Dep't of Educ.*, No. 22-5807, 2024 WL 2984295 (6th Cir. June 14, 2024).

C. The new rule's similar lack of authority

333. But in the new rule, according to HHS, "[u]nder Bostock's reasoning, laws that prohibit sex discrimination also prohibit discrimination on the basis of gender identity." 89 Fed. Reg. at 37,673.

334. The Supreme Court's decision in *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020), interpreted Title VII's prohibition on employment discrimination "because of sex." In that case, the Supreme Court held that Title VII's prohibition of discrimination "because of sex" prevents an employer from firing an employee simply "for being homosexual or transgender." *Id.* at 651–52. An employer who fires a male employee "for no reason other than the fact he is attracted to men … discriminates against him for traits or actions it tolerates in his female colleague," and vice versa. *Id.* at 660.

335. The *Bostock* Court, though, "proceed[ed] on the assumption that 'sex' … refer[s] only to biological distinctions between male and female." *Id.* at 655.

336. *Bostock* did not address Section 1557 or Title IX. Indeed, *Bostock* expressly declined to "prejudge" any issues pertaining to bathrooms, healthcare, insurance, "or anything else of the kind" under any other nondiscrimination law. *Id.* at 681.

337. Post-*Bostock* guidance issued by the Department of Education's Office of the General Counsel emphasized that Bostock did not affect the longstanding meaning of Title IX's reference to "sex."[100]

338. As many federal courts have held, "the rule in Bostock extends no further than Title VII." *Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021) ("[T]he Court in *Bostock* was clear on the narrow reach of its decision and how it was limited only to Title VII itself."). And "it does not follow that principles announced in the Title VII context automatically apply in the Title IX context." *Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021).

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[100] *See* Reed D. Rubinstein, Memo. for Kimberly M. Richey, Acting Assistant Secretary of the Office for Civil Rights, re: *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731 (2020) (Jan. 8, 2021), https://perma.cc/Q9YC-Q4Y2.

339. HHS's reading falls outside the range of reasonable interpretations of the statutory text because it purports to resolve a policy issue of major political significance without clear congressional authority, *see West Virginia v. EPA*, 597 U.S. 697, 721–24 (2022), and fails to construe "on the basis of sex" "to avoid serious constitutional doubts," *Brawner v. Scott Cnty.*, 14 F.4th 585, 592 n.2 (6th Cir. 2021) (quoting *FCC v. Fox Tel. Stations, Inc.*, 556 U.S. 502, 516 (2009)).

XI. The rule's immediate compliance requirements

340. The rule's prohibition on discrimination on the basis of gender identity went into effect on July 5, 2024.

A. New policies, notices, assurances of compliance, and certifications

341. The rule prohibits covered entities from having or applying policies contrary to the rule.

342. The rule requires covered entities to adopt and publish policies that comply with the rule.

343. The rule requires covered entities to have policies consistent with the rule and to state in their policies that they will not discriminate on the basis of sex or disability, which the rule defines to mean gender identity.

344. The rule requires covered entities to provide an updated notice of nondiscrimination to patients consistent with stating that they will not discriminate on the basis of gender identity.

345. The notice to patients must be provided annually and on request.

346. The notice must be posted at a conspicuous location on the covered entity's health program or activity website and in clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice.

347. The rule prohibits covered entities from stating to patients that they will engage in actions or omissions inconsistent with the rule's prohibitions on discrimination on the basis of gender identity.

348. The rule requires covered entities to train or reeducate themselves and their employees to comply.

349. Under the rule, covered entities must contemporaneously document their employees' completion of the training and maintain that documentation for at least three calendar years.

350. Under the rule, covered entities must submit an assurance of compliance to HHS that they have adopted the rule's new policies as a contractual condition of receipt of federal funding, or else they will be unable to apply or maintain eligibility for federal funding.

351. Under the assurance, covered entities must agree to comply with the rule, including the prohibition on discrimination on the basis of gender identity.

352. This assurance must be submitted by clinics seeking to receive any federal health funding from HHS, including to receive Medicaid or CHIP certification.

353. Assurance of compliance submitted by clinics prior to issuance of the rule, including assurances made by clinics for Medicaid or CHIP certification, will now be read by HHS to encompass a contractual assurance that MCC will comply with the rule.

354. Every time a covered entity requests a federal health funding payment from HHS it impliedly certifies to the federal government that it follows governing regulations, and the rule imports the prohibition on gender-identity discrimination into those implied certifications.

355. Covered entities unwilling to agree to make such an assurance or certification of compliance cannot apply for or maintain eligibility for federal health funding from HHS.

356. Each required assurance or certification that an entity makes to receive federal health funding from HHS will create or extend contractual obligations requiring the covered entity to comply with the rule.

357. Under the rule, a covered entity that employs 15 or more people must appoint a "Section 1557 Coordinator" in charge of compliance with the rule, must implement written grievance procedures for receiving and resolving allegations of any action that the rule would prohibit, must keep all grievances for three years, and must not disclose the identity of any person who files a grievance against the entity.

B. The rule's creation of new liability risks

358. The rule creates new risks that covered entities could lose federal funding or face criminal and civil liability.

359. Failure to follow the rule and its interpretation of Section 1557, Title IX, and HHS regulations risks the burdens and costs of federal investigations and enforcement proceedings.

360. Failure to follow the rule and its interpretation of Section 1557, Title IX, and HHS regulations risks disallowance, exclusion, suspension, and debarment from receipt of federal funding.

361. Failure to follow the rule and its interpretation of Section 1557, Title IX, and HHS regulations arguably risks liability under a cause of action in civil litigation, including in suits brought by the public.

362. The rule allows for enforcement by a private cause of action.

363. Litigants may arguably cite the rule as a binding interpretation of Section 1557 under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Or maybe not. *Loper Bright Enters. v. Raimondo*, 22-1219, 2024 WL 3208360, at *22 (U.S. June 28, 2024) ("*Chevron* is overruled.").

364. The rule subjects States to private suits by employees and patients, purporting to waive the States' sovereign immunity in these areas.

365. Failure to follow the rule and its interpretation of Section 1557, Title IX, and HHS regulations arguably risks civil and criminal liability under federal healthcare-fraud and false-claims statutes and regulations.

366. The rule creates these arguable healthcare-fraud and false-claims liability risks because the rule requires covered entities to operate their practices in accord with the rule and to sign assurances of compliance as a contractual condition of receiving funds.

367. The False Claims Act, for example, makes a person liable for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

368. A "claim" means "any request or demand, whether under a contract or otherwise, for money or property" presented to an officer of the United States or a recipient of federal funding (like a state administering its state Medicaid program). 31 U.S.C. § 3729(b)(2)(A).

369. Under these laws, covered entities must ensure that they are presenting accurate and appropriate claims, such as when covered entities seek payment for providing healthcare to Medicaid patients.

370. As HHS warns physicians, "When you submit a claim for services performed for a Medicare or Medicaid beneficiary, you are filing a bill with the

Federal Government and certifying that you have earned the payment requested and complied with the billing requirements."[101]

371. A covered entity is arguably liable for express or implied false certifications when a provider submits a claim for payment but does not or intends not to comply with the rule's gender-identity nondiscrimination requirement, or fails to disclose such noncompliance.

372. Such a covered entity arguably incurs this liability each time it submits a claim for federal payment or accepts federal financial assistance.

373. HHS considers compliance with the rule and its interpretation of Section 1557, Title IX, and HHS regulations material in its payment decisions.

374. HHS is substantially likely to deem a provider's request for payment misleading if the provider is not in compliance with the rule and its interpretation of Section 1557 and its implementing regulations.

XII. ACPeds' injuries from the rule

375. ACPeds and its members are in the crosshairs of the rule.

376. ACPeds has an urgent need for judicial relief to shield its members' medical practices and their patients from HHS's harmful rule.

377. ACPeds members provide high-quality medical services to children without discrimination on the basis of sex or any other characteristic prohibited by statute.

378. ACPeds' position is that a child with medical needs, such as a sore throat or a broken arm, should be given the best medical care possible, regardless

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[101] *Physician Relationships With Payers*, Office of Inspector General, HHS, https://oig.hhs.gov/compliance/physician-education/i-physician-relationships-with-payers/ (last visited June 29, 2024) (emphasis omitted).

of his or her identity. But its members cannot harm patients, nor can they lie to them.

379. Based on the medical science and ethical medical practice, ACPeds members categorically do not provide medical interventions or referrals for, and do not facilitate or speak in ways that affirm the legitimacy of, the practice of "gender transition."

380. ACPeds members are committed to following state laws that restrict gender-transition procedures for minors.

381. ACPeds members seek to continue to be free to follow ACPeds' positions in their medical practice by declining to provide "gender-affirming care" or "gender-transition procedures," and to share their complete medical judgment with patients on gender-transition procedures.

A. ACPeds' categorical views on gender transitions

382. ACPeds and its members have deep, substantial, science-based objections to "gender-transition" efforts.

383. Based on current scientifically sound research, ACPeds holds the view that "gender-affirming care" and "gender-transition" procedures harm patients—particularly children—and can result in infertility, cardiovascular disease, poor bone health, and other chronic illnesses, and that medical science does not support the provision of such procedures.

384. They hold the view that sex is a biological, immutable characteristic—a scientific reality, not a social construct.

385. They hold the view that to eliminate sex-specific private spaces violates fundamental rights of all persons to privacy, dignity, safety, and a secure environment.

386. Based on the best scientific evidence, ACPeds members categorically oppose providing, referring for, facilitating, or speaking in favor of similar services for "gender-transition" procedures.

387. ACPeds members categorically oppose asking for patients' gender identity, or charting or coding them according to their gender identity instead of their sex according to biology.

388. ACPeds members categorically oppose providing advice, referrals, or care that "affirms" gender transition, or participates in "social transition" by, for example, the use of "preferred pronouns."

389. Specifically, ACPeds members' categorical exclusion of providing, facilitating, or affirming "gender-transition" interventions, and its commitment to complying with state law, precludes them from:

A. Prescribing puberty blockers, cross-sex hormone therapies, or other similar ongoing interventions to treat gender dysphoria or for transition efforts;

B. Performing surgeries to treat gender dysphoria or for transition efforts, including:

i. Removing healthy breasts, uteruses, or ovaries from females who purport to identify as males, nonbinary, or who otherwise do not identify as females (hysterectomies, mastectomies, and oophorectomies);

ii. Removing healthy vaginal tissue from females who purport to believe themselves to be males, nonbinary, or otherwise not to be

female, and creating for them a faux or cosmetic penis (phalloplasties and metoidioplasties);

iii. Removing healthy testicles or scrotums from males who purport to believe themselves to be female (orchiectomies or scrotectomies);

iv. Performing a process called "de-gloving" to remove the healthy skin of a male's penis and using it to create a faux vaginal opening or vulva (vaginoplasties and vulvoplasties);

v. Removing healthy internal or external genitals from any person to create a "smooth gender-neutral look" (nulloplasties or nullification surgeries); and

vi. Performing other procedures sought to make a person resemble the opposite sex or no sex, such as facial, chest, neck, skin, hair, or vocal modification;

C. Saying in their professional opinions or through staff that these transition efforts are the standard of care, are safe, are beneficial, are not experimental, are not cosmetic, or should otherwise be recommended;

D. Offering to perform, provide, or prescribe the above such transition interventions, procedures, services, or drugs, including in published statements;

E. Referring patients for any and all such interventions, procedures, services, or drugs;

F. Refraining from expressing their views, options, and opinions to patients when those views are critical of transition efforts;

G. Refraining from informing patients or the public that they do not provide transition procedures, including by refraining from sharing this information in patient conversations or on websites;

H. Treating and referring to patients according to gender identity and not sex;

I. Saying that sex or gender is nonbinary or on a spectrum;

J. Using language affirming any self-selected gender identity inconsistent with sex or the biological binary;

K. Asking patients to share their gender identity or pronouns beyond basic inquiries into the patient's sex;

L. Being forced to use patients' self-selected pronouns according to gender identity, rather than using no pronouns or using pronouns based on sex;

M. Creating medical records and coding patients and services according to gender identity not sex;

N. Saying that males can be pregnant or give birth;

O. Affirming or endorsing gender-transition efforts;

P. Allowing patients to access single-sex programs and facilities, such as well-woman and OB/GYN care, lactation training, induction, and

medical care, breastfeeding support groups, educational sessions, maternity homes, changing areas, restrooms, communal showers, or other single-sex programs and spaces, by gender identity and not by sex;

Q. Repealing or modifying their policies, procedures, and practices of not offering to perform or prescribe the above procedures, drugs, and interventions for transition efforts; and

R. Providing assurances of compliance, compliance reports, express or implied certifications of compliance, and notices of compliant policies, or posting notices of compliant policies in prominent physical locations as to the rule's gender-identity requirements.

390. The above list is not exhaustive, but each is potentially required by the HHS rule.

391. ACPeds members communicate these policies and positions to patients.

392. The rule, however, requires ACPeds members to do or say all these things.

B. The rule's effect on ACPeds members' medical practices

393. Most ACPeds members are or work for a covered entity under the 1557 rule.

394. Most ACPeds members participate in health programs and activities receiving federal financial assistance.

395. Most ACPeds members treats patients who provide payment through federally subsidized healthcare programs such as Medicaid, Medicare, and CHIP.

396. Most ACPeds members bill Medicaid and CHIP for patient care, and comply with paperwork, certification, and assurances to do so.

397. The rule impacts ACPeds members in their practice of medicine as individual physicians who are regulated by the rule and in the practice of some of them as corporate principals and owners of medical practices that the rule regulates, for example in their duty to create, implement, and train staff on policies and to ensure compliance of their medical practices.

398. ACPeds members offer a full array of services to help children maintain good health. These services include, but are not limited to, well-child care exams, sports physicals, newborn care, vision and hearing screenings, immunizations, sick child diagnosis and treatment, dietary and nutrition guidance, lab testing, and prescription of medication.

399. ACPeds members treat or refer some patients for puberty blockers or sex hormones for sound medical and therapeutic reasons, such as labial adhesions, cases of precocious puberty, or pituitary failure that prevented naturally occurring puberty.

400. ACPeds members provide or refer for hormones for various medical reasons.

401. This broad scope of services place ACPeds members within the scope of the rule.

402. But ACPeds members oppose providing, referring for, facilitating, or speaking in favor of similar services for "gender-transition" procedures.

403. The rule forces most ACPeds members to violate state laws prohibiting gender transitions for minors.

404. The rule seeks to preempt state laws that protect ACPeds members from facilitating gender-transition procedures—both state laws that restrict these

procedures themselves and state laws that protect healthcare institutions' rights to decline to participate in these procedures.

405. ACPeds members provide their complete medical judgment to patients when asked to advise on gender-transition procedures. But ACPeds members categorically do not provide advice, referrals, or care that "affirms" gender transition, or participates in "social transition."

406. ACPeds members use pronouns for patients that accord with the patients' sex according to biology (male or female). ACPeds members code and chart patients by sex.

407. ACPeds members categorically do not voluntarily ask for patients' gender identity, or chart or code patients according to their gender identity instead of their sex according to biology. ACPeds members, for example, do not use "preferred pronouns" in medical records.

408. The rule forces most ACPeds members to abandon policies categorically excluding the provision of "gender transitions."

409. The rule requires ACPeds members to adopt, give notice of, follow, or post a policy that they do not discriminate on the basis of gender identity as understood by the rule. The rule will also require ACPeds members to reverse and pull down their existing policies on "gender transitions."

410. ACPeds members oppose complying with the rule's requirement that they follow or adopt a "nondiscrimination" policy on "gender identity," or provide notice that they do not discriminate on the basis of "gender identity."

411. The rule will require ACPeds members to provide training to employees to ensure their compliance with the rule.

412. ACPeds members have provided past assurances of compliance or certifications as required by HHS to be eligible to receive federal financial assistance.

413. But the rule will deem ACPeds members' past assurances of compliance or certifications as if they encompass compliance with the rule's new gender-identity mandate.

414. The rule will likely require ACPeds members to submit new assurances of compliance or certifications that it complies with the rule.

415. The rule will subject ACPeds members to significant financial and legal liability if it continues its current practices instead of engaging in compliance measures under the rule.

416. The rule threatens ACPeds members with expulsion from participation in Medicaid, Medicare, and CHIP, and other federal financial assistance programs.

417. It would cause ACPeds members significant financial harm to lose eligibility to participate in federal healthcare programs such as Medicare, Medicaid, and CHIP.

418. The rule arguably exposes ACPeds members to civil penalties, criminal penalties, damages, investigative burdens, and document demands.

419. The burdens of being investigated for alleged or suspected violations—or reviews over such non-compliance—are severe, imposing significant costs of time, money, attorney's fees, and diversion of resources that these healthcare providers could use to continue providing quality medical care and to continue receiving compensation for the same.

420. Compliance with the rule also presents risks to ACPeds members' patients—including life-threatening risks—by creating a risk of confusion as to a patient's sex that can lead to medical errors.

421. Compliance with the rule would present risks to ACPeds members' patients—including life-threatening risks—by requiring that necessary procedures and inquiries be omitted by ACPeds members because those are associated with

the patient's sex and not the patient's gender identity. For example, if a female's chart is coded with a "gender identity" as male and the patient presents with abdominal pain, the doctor may not check for pregnancy because males cannot get pregnant but a female who identifies as a male can.

422. Providing required "gender-transition" services will cause life-altering harm to children that is often irreversible without any scientific basis to suggest it helps with any psychological distress from gender incongruence that often resolves with puberty.

423. Compliance with the rule would lead to medically unnecessary procedures, harming patients, wasting the time and money of providers, patients, and insurers, and draining resources that could be better spent elsewhere. For example, some basic examinations on wellness checks are sex-specific (Growth Charts are sex-specific, pelvic exams for females and testicular exams for males) that could not be done if the patient is treated exclusively based on "gender identity" as required by the rule.

424. Compliance with the rule would cause ACPeds members to incur increased costs from defending against Defendants' investigation and enforcement actions.

425. Compliance with the rule would force ACPeds members to force their employees against their will to perform, refer for, facilitate, speak in favor of, or not speak against, "gender transitions."

426. The rule imposes the following no-win choice on ACPeds members: (1) abandon or violate their policies and incur the costs of compliance with the rule; (2) maintain their positions and practices and risk continuing liability and investigative demands with no promise they will be deemed exempt from the loss of eligibility for participation in federal financial assistance programs; or (3) exit the medical field and abandon their patients.

427. If ACPeds members do not comply with the rule, they will have to defend themselves from investigations and enforcement actions, losing time, money, and resources that they could use for patients' medical care.

428. If ACPeds members do not comply with the rule, but HHS nevertheless requires them to do so, ACPeds members will find it difficult to be employed in the field of medicine, as almost all medical practices receive federal financial assistance from HHS.

429. The rule will place intense strain on the healthcare system and cause immense human suffering and higher medical costs.

430. Imposing the rule will deprive patients who want to receive care from ACPeds members.

431. These effects will exacerbate shortages of medical professionals, reducing the availability of healthcare providers to care for underserved, low-income, and rural patients.

432. Imposing the rule will deprive patients who want to receive care from ACPeds members.

433. The rule threatens to drive healthcare professionals out of medicine and dissuade students from choosing to practice medicine—reducing care for underserved, low-income, and rural patients.

434. If the number of physicians who take federal funding is reduced, they cannot easily be replaced, and it will reduce access to care for federally funded patients. Medicaid patients already have less access to primary and specialty care than privately insured patients.[102] Physicians historically have been significantly

[102] Walter R. Hsiang et al., *Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis*, 56 Inquiry 1, 4 (2019), https://journals.sagepub.com/doi/pdf/10.1177/0046958019838118.

less likely to accept new patients covered by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent).[103]

XIII. The rule's effect on Dr. Dan Weiss

435. As an illustration of the harm of the rule, one representative ACPeds member is Dr. Daniel Weiss.

436. Dr. Weiss cares for all patients with respect and without unlawful discrimination. He provides all patients the best evidence-based treatment.

437. Dr. Weiss share the views of ACPeds. Dr. Weiss wants to continue to be free to follow ACPeds' positions in his medical practice and to share his complete medical judgment with patients on gender-transition procedures.

438. Dr. Weiss categorically objects to providing, referring for, or affirming medical procedures to "transition" a patient's gender.

439. Dr. Weiss categorically opposes adopting, following, or providing a policy, notice, assurance of compliance, or certification in their practice that says he does not "discriminate" on the basis of gender identity.

440. Dr. Weiss categorically opposes using a patient's self-selected gender identity or pronouns in medical records.

441. Dr. Weiss categorically opposes allowing males to access female private spaces (and vice versa), such as by ensuring the assignment of medical chaperones by gender identity.

442. Dr. Weiss holds these positions as a matter of sound medical judgment and ethics. He has come to hold his positions based on his experience and his knowledge of the science. His position is not based on religious beliefs.

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[103] MACPAC, *Physician Acceptance of New Medicaid Patients*, *supra* note 24, at 2 (collecting data on the percentage of doctors accepting new patients in each category).

443. Utah limits gender-transition procedures for minors. When it comes to minor patients, the rule forces Dr. Weiss to choose between (a) following state law and violating the rule, or (b) following the rule and violating state law. Dr. Weiss will not violate state law.

444. Dr. Weiss is actively practicing medicine and seeing patients.

445. Dr. Weiss provides services to patients reimbursed by Medicaid or Medicare.

446. Dr. Weiss has treated and regularly treats patients who identify as transgender, non-binary, or otherwise contrary to their sex, and he anticipates continuing to treat such patients in their medical practice. For example, one current patient has gender dysphoria, and he is treating this patient for a thyroid problem separate from other secondary sex characteristics and gender dysphoria. He is happy to help this patient with the thyroid problem.

447. Dr. Weiss has provided and regularly provides or refers for hormones for medically indicated, non-transition reasons. He has provided and regularly provides sex hormones for medical reasons to his new and existing patients. He prescribes oral progesterone (Provera) to women who have infrequent menstrual periods to prevent excessive uterine lining buildup. He prescribes testosterone (by injection or as a topical gel) for men with very low levels of testosterone. He will then monitor the patient's blood levels of testosterone to ensure that the testosterone levels are at target. He also monitors for adverse reactions to testosterone, such as excessive blood cell count or an increase in prostate specific antigen (PSA, a prostate test).

448. Dr. Weiss has received requests from patients to provide or refer for transition procedures, and he expects to receive similar patient requests for transition procedures or referrals for transition procedures in the future. His front

desk employs a screening mechanism in which these requests are directed to other willing providers.

449. These similar patient requests for transition procedures or for gender-transition referrals are requests that Dr. Weiss would be legally required to make under the rule but are unable to do so with sound medical judgment. As a matter of sound medical judgment, if a patient asked for these procedures at an appointment, he would have to politely decline each request. He would respectfully share his medical judgment and explain that hormonal interventions or surgical gender-transition procedures are not beneficial.

450. Dr. Weiss will not provide or refer for gender-transition procedures.

451. The rule would interfere with his medical practice by prohibiting his current screening mechanism. The rule would consider gender-transition efforts to be within his scope of practice and expertise. The rule would require his scheduling department to include him as a doctor to whom it will send these patients. Then the rule would require him to provide these patients gender-transition interventions and gender-transition referrals—not just for adult patients but for all patients, even patients under 18 years of age. Sound medical judgment prevents him from doing so.

452. Previously, when he worked in a different healthcare system, he had not come to this view of the science. In the past, in this different role, he did not employ a screening mechanism and he provided opposite-sex hormones to about 100 adult gender dysphoria patients. He provided testosterone for women. He prescribed estrogen for men along with androgen blockade in order to block male hormone action to make males appear more feminine. During this time, some patients wanted mastectomies or genital surgeries for gender-transition purposes. He referred them to surgeons for these surgeries. Various patients received mastectomies or genital surgeries. In 2013 he stopped providing or referring for

hormonal or surgical interventions for gender dysphoria. He came to realize that these interventions lack benefit and pose potential harm, and he realized that patients had minimal or inadequate psychological evaluation. Based on his experience and based on his knowledge of the scientific literature, in his medical judgment, no high-quality evidence supports hormonal or surgical interventions for gender dysphoria. Thus, as a categorical matter, he no longer provides or refers for these procedures, and will not do so, based on experience and medical judgment.

453. Dr. Weiss has freely shared this complete medical judgment with patients on transition procedures—explaining to them the best science and medical information on the subject.

454. Recently a female patient unexpectedly sought testosterone during an appointment (a request she had not disclosed in advance to the scheduling department at the screening stage). Dr. Weiss shared with her the science supporting his medical judgment, but she was very disappointed to learn that he would not prescribe her testosterone.

455. Dr. Weiss will not self-censor his opinions on transition efforts if the rule goes into effect.

456. Dr. Weiss regularly uses pronouns for patients that accord with the patients' biological and binary sex, and he codes and charts patients by sex.

457. Dr. Weiss is regularly expected by patients to use self-selected pronouns contrary to the patient's sex in medical records, and he expects to receive similar patient requests in the future.

458. Under the rule, Dr. Weiss would be legally required to censor or alter his speech and records in these patient interactions but he is unable to do so with sound medical judgment.

459. Dr. Weiss has provided and continues to provide access to medical chaperones according to a person's biological and binary sex but he does not provide access by gender identity.

460. Dr. Weiss would be legally required under the rule to ensure access to medical chaperones by gender identity but he is unable to do so with sound medical judgment.

461. The new rule applies to all operations of his healthcare system and medical practice, both the treatment of patients in Medicare or Medicaid programs and the treatment of patients who are not in these programs. Like all ACPeds members, his objections do not depend on the source of the funds by which patients pay.

462. The new rule applies without regard for the age of the patient. Like all ACPeds members, his medical position on gender-transition procedures does not change depending on the age of the patient.

463. Dr. Weiss's employer will immediately be required by the rule to adopt, give notice of, and post a nondiscrimination policy on gender identity if the rule goes into effect.

464. Dr. Weiss will be required to follow this employer nondiscrimination policy on gender identity if the rule goes into effect.

465. Dr. Weiss's employer has provided past notices, assurances of compliance, or certifications as required by HHS, and it is also responsible for providing updated policies, notices, or assurances of compliance under the rule.

466. Dr. Weiss refuses to comply with the rule's policy, notice, assurance of compliance, and certification requirements and adopt the rule's gender-identity policies.

467. No other person can make the required assurance of compliance or other certification on his employers' behalf, without arguably making a false or

misleading statement of claim, given that Dr. Weiss is not and seeks to continue not being in full compliance with the rule.

468. Dr. Weiss will be required within one year to receive training to ensure his compliance with the rule if the rule goes into effect. He will refuse to do so.

469. Because he will not comply with the rule, Dr. Weiss faces the prospect of no longer caring for his patients, being fired from his employment, and being unable to practice medicine in most settings.

470. Dr. Weiss has spent time to learn about the rule and to develop the necessary plans to avoid noncompliance. It has already taken him at least an hour to read the rule and obtain compliance advice, and plan for the significant changes from the rule to daily medical practice, resulting in a value of $120 for an hour of lost time. If the rule goes into effect, he will spend even more resources for these purposes. He would not have to do any of this but for the rule.

471. At the time of when decisions and actions are required about compliance with the rule's policy, notice, assurance-of-compliance, certification, training, and other requirements, Dr. Weiss will not know whether HHS will exempt him or his employer from enforcement of the rule's gender-identity provisions.

472. Dr. Weiss adopted a personal policy statement for his medical practice that explains that he does not offer, refer for, or endorse gender-transition efforts. It states: "I am a medical doctor committed to providing the best evidence-based care to every patient, no matter how the patient identifies. I will never harm a patient or withhold my best medical advice. No sound evidence supports providing gender-transition procedures to attempt to make a person resemble the opposite sex, such as puberty blockers, cross-sex hormones, or surgical procedures. These experimental and cosmetic procedures harm patients and can carry serious, long-

term risks. The best evidence suggests that these procedures do not reduce suicide or suicidality. Based on personal experience, the scientific literature, and sound medical judgment, as a categorical matter, I do not offer, refer for, or endorse gender-transition efforts. I use correct biological medical terminology in my medical records and notes, including biological pronouns. I provide chaperones as needed based on sex. This approach reduces the risk of medical errors and protects all patients' privacy and safety."

473. Dr. Weiss currently informs patients and potential patients that he does not offer, refer for, or endorse gender-transition efforts by posting his policy statement in a visible place at his personal workspace at his employment setting. Dr. Weiss wants to, but out of compliance with the rule on its specified dates, will no longer inform patients and potential patients about this policy by posting it in his workspace. If the court does not protect him from the rule, he will remove his policy statement from his office workspace in compliance with the rule.

XIV. The rule's effect on ACPeds

474. The rule does more than just coerce good doctors to harm their patients. It also impairs ACPeds' educational and professional mission.

475. ACPeds is dedicated to ensuring that its members can provide excellent healthcare in line with sound medical judgment. Part of the ACPeds educational mission also includes informing members of major developments affecting their practice of medicine. It is also part of the ACPeds professional mission to support and enable ACPeds members to practice sound medicine.

476. The rule undermines ACPeds' efforts to advocate for solid evidence-based medicine because it establishes transition-based experimentation as nationwide standard of care. The rule prevents ACPeds members from practicing medicine in an environment free from federal mandates in favor of gender-

transition procedures. The rule creates an inaccurate public impression that gender-transition efforts are not harmful, dangerous, cosmetic, or experimental.

477. ACPeds will need to increase efforts to educate doctors about their professional freedom to practice sound medicine and otherwise.

478. ACPeds expended resources opposing the adoption of the rule.

XV. ACPeds expects to receive member requests for guidance and help in response to the rule. The rule inflicts compliance costs on Plaintiffs

479. With the rule set to take effect on July 5, 2024, Plaintiffs face imminent, unrecoverable compliance expenses and the risk of liability in private suits.

480. These compliance costs and efforts will be substantial—as the rule itself acknowledges.

A. Financial costs for paying for "gender-transition" procedures

481. The States will have to incur the financial costs of paying for "gender-transition" procedures in their health plans.

482. The average cost for coverage for "gender-transition" procedures, just in reimbursements, according to one study, is $1,776 per person per year.[104] If anything, that understates the cost because the cost of a single surgery can be as much as $63,000.[105]

483. According to another study used by HHS in its economic-impact analysis of the rule, "the average cost of transition-related care (surgery, hormones,

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[104] Kellan Baker & Arjee Restar, *Utilization and Costs of Gender- Affirming Care in a Commercially Insured Transgender Population*, 50:3 J Law Med Ethics 456, 465 (2022).

[105] *Id*. at 463.

or both) per person needing treatment was $29,929 over 6.5 years," or approximately $4,600 per year.[106]

484. The number of individuals in Missouri 13 years or older who identify as transgender has been estimated by the Williams Institute at UCLA to be 12,400.[107]

485. Even assuming only half these individuals seek "transition" procedures, and 15 percent of those 6,200 persons are on Medicaid,[108] 930 people would seek coverage. Then using the conservative estimate of $1,776 per person per year for the expense of coverage, the yearly cost of the rule would be a conservative estimate of $1,651,680, not including costs of interventions already completed that individuals may try to bill against the State.

486. The number of individuals in Utah ages 13 to 17 who identify as transgender has been estimated by the Williams Institute at UCLA to be 2,100.[109] Even assuming that only half these individuals seek "transition" procedures, and 11 percent of those 1,050 persons are on Medicaid,[110] 115 people would seek coverage. Then using the conservative estimate of $1,776 per person per year for the expense of coverage, the yearly cost of the rule would be a conservative estimate

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[106] Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care*, 373 New Eng. J. Med. 1089 (2015).

[107] Williams Institute, Demographic Characteristics, Missouri, https://williamsinstitute.law.ucla.edu/subpopulations/transgender-people/.

[108] *Medicaid in Missouri,* Kaiser Family Foundation 1 (2023), https://files.kff.org/attachment/fact-sheet-medicaid-state-MO.

[109] Williams Institute, Demographic Characteristics, Utah, https://williamsinstitute.law.ucla.edu/subpopulations/transgender-people/

[110] *Medicaid in Utah,* Kaiser Family Foundation 1 (2023), https://files.kff.org/attachment/fact-sheet-medicaid-state-UT.

of $204,240, not including costs of interventions already completed that individuals may try to bill against the State.

487. The number of children in Arkansas 13 to 17 who identify as transgender has been estimated by the Williams Institute at UCLA to be 1,800.[111] Even assuming only half these individuals seek "transition" procedures, and 27 percent of those 900 persons are on Medicaid,[112] 243 people would seek coverage. Then using the conservative estimate of $1,776 per person per year for the expense of coverage, the yearly cost of the rule would be a conservative estimate of $431,568 not including costs of interventions already completed that individuals may try to bill against the State.

488. The number of individuals in Iowa 13 to 17 who identify as transgender has been estimated by the Williams Institute at UCLA to be 2,100.[113] Even assuming only half these individuals seek "transition" procedures, and 20 percent of those 1,050 persons are on Medicaid,[114] 210 people would seek coverage. Then using the conservative estimate of $1,776 per person per year for the expense of coverage, the yearly cost of covering all transition procedures for minors would be a conservative estimate of $372,960 not including costs of interventions already completed that individuals may try to bill against the State.

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[111] Williams Institute, Demographic Characteristics, Arkansas, https://williamsinstitute.law.ucla.edu/subpopulations/transgender-people/

[112] *Medicaid in Arkansas,* Kaiser Family Foundation 1 (2023), https://files.kff.org/attachment/fact-sheet-medicaid-state-AR.

[113] Williams Institute, Demographic Characteristics, Iowa, https://williamsinstitute.law.ucla.edu/subpopulations/transgender-people/

[114] *Medicaid in Iowa,* Kaiser Family Foundation 1 (2023), https://files.kff.org/attachment/fact-sheet-medicaid-state-IA.

489. The number of children in North Dakota aged 13 to 17 who identify as transgender has been estimated by the Williams Institute at UCLA to be 500.[115] Even assuming only half these children seek transition procedures, and 10 percent of those 250 children are on Medicaid,[116] 25 children would seek coverage. Then using the low-end estimate of $1,776 per person per year for the expense of coverage, the yearly cost of covering all transition procedures for minors would be a conservative estimate of $44,000, not including the costs of interventions already completed that individuals may try to bill against the State.

490. Thousands more individuals who identify as transgender are enrolled in each state's employee and retiree health plans, which will cause each State to incur further costs for the same coverage in these plans.

491. Each State will also face even greater costs to the healthcare system from the serious negative side effects caused by these procedures. Much of the care for these severe, life-long medical complications would be covered through Medicaid for decades over the course of these individuals' lives.

492. This cost, to be sure, pales in comparison with the human cost of aiding and abetting experimental procedures that could render thousands of children infertile for life.

493. If States do not comply, enforcement of the rule threatens to collectively strip Plaintiff States of tens of billions of dollars in federal HHS funds and to impose substantial penalties through private suits. This severe financial exposure endangers important health programs that serve some of the Plaintiff States' most vulnerable residents.

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[115] Williams Institute, Demographic Characteristics, North Dakota, https://williamsinstitute.law.ucla.edu/subpopulations/transgender-people/.

[116] *Medicaid in North Dakota,* Kaiser Family Foundation 1 (2023), https://files.kff.org/attachment/fact-sheet-medicaid-state-ND.

494. The rule thus will undoubtedly have a "substantial" fiscal effect on Plaintiff States. 89 Fed. Reg. at 37,683.

B. The rule's other estimated categories of compliance costs

495. The rule estimates that covered entities (such as the States and ACPeds members) will incur financial costs for compliance, some of which are likely to occur even before the rule's effective date.

496. The rule estimates that each covered entity will incur up-front costs from revising policies, training staff, providing notices, and keeping records of employee training.

497. The rule states that to comply with its training requirements, covered entities will train each employee who interacts with the public or with patients, and that the training would last an hour.

498. The rule estimates that the cost of revising relevant policies and procedures to comply with the rule will result in a one-time cost of $65 million across all covered entities. 89 Fed. Reg. at 37,680.

499. The rule estimates that each covered entity will incur annual or ongoing costs to train or refresh the training of new or returning employees, to maintain records of training and grievances, and to provide notices.

500. The rule predicts the initial cost of training employees on the rule across all covered entities will be more than $927 million, with ongoing annual training estimated to cost another $309 million per year. *Id.* at 37,679, 37,680. And it estimates that required annual recordkeeping will cost millions more. *Id.* at 37,682.

501. The rule estimates that covered health plans will incur the costs of paying for "gender-affirming care coverage."

502. The rule estimates $136 million in increased healthcare costs for this coverage. 89 Fed. Reg. at 37,683.

503. Defendants admit in the rule that entities with more than 15 employees will incur compliance costs even higher than smaller employers.

504. Each State is a covered entity with more than 15 employees that falls within those entities that Defendants estimate are subject to compliance costs caused by the rule.

C. The rule's total estimated compliance costs

505. In total, HHS estimates that the rule will cost covered entities, at a minimum, more than $1.1 billion in 2024 and at least half a billion dollars every year thereafter. 89 Fed. Reg. at 37,684. Virtually all the first-year expenses are for covered entities to conduct new training, change policies and procedures, provide notices, and adopt new recordkeeping practices, and HHS estimates that these expenses alone will encompass more than $300 million annually. *Id*.

506. While substantial, this billion-dollar up-front price tag, with a continuing half-a-billion bill each year, is nonetheless unduly low for two reasons.

507. *First*, HHS unrealistically assumes that its nationwide mandate to pay for gender-transition procedures will cost nothing in the first year and then will be "immaterial" and impose only "a small impact" of $136 million in increased public and private healthcare costs nationwide every year thereafter. HHS bases this rosy assumption on a hope that paying for these procedures will somehow result in cost savings and on an unsupported guess that many health plans already cover these procedures. 89 Fed. Reg. at 37,683.

508. *Second,* HHS assumed without explanation that all covered entities and their employees will comply with the rule, so HHS did not even consider the costs of the rule for covered entities and employees who lose their ability to

participate in federally funded healthcare programs—or the costs for patients who experience a reduction in healthcare access.

D. Plaintiffs' compliance costs

509. The rule imposes compliance costs that covered entities must start incurring now unless the rule is enjoined.

510. The States and ACPeds members have already incurred some compliance costs from the rule.

511. These include reviewing the rule and obtaining legal advice about compliance and legal options.

512. The rule requires Plaintiffs (including ACPeds members) to spend time and money to comply with the rule that it would not expend but for the rule.

513. The rule will, at minimum, impose these costs on Plaintiffs by requiring each Plaintiff to: familiarize itself with the rule, draft, adopt, and publish a "nondiscrimination" policy on "gender identity"; designate a 1557 coordinator and draft grievance policies; revise clinic policies to comply with the rule; plan and create training documents and train employees to comply with the rule; keep records of training; and keep records of patient grievances.

514. The rule has caused and continues to cause ACPeds and its members to divert organizational resources and staff time to review the rule, consult legal counsel, and engage in statements and educational efforts towards staff and patients to mitigate confusion that the rule has caused about its application and its inconsistency with other federal and state laws.

515. Plaintiffs must continue incurring further compliance costs under the rule, both prior to and after its effective date, unless this Court issues an injunction.

516. Plaintiffs will avoid most compliance costs from the rule if this Court preliminarily enjoins it and ultimately issues permanent relief.

XVI. Urgent need for judicial relief

517. Defendants HHS and OCR are federal agencies subject to the APA.

518. The APA allows a person "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action" to seek judicial review of that action. 5 U.S.C. § 702.

519. Plaintiffs suffer legal wrong and adverse effects from the rule.

520. Plaintiffs are regulated parties under the rule.

521. The day a rule is adopted and you're a regulated party, even if nothing has happened to you by the agency, you have standing to sue. That happens all the time.

522. The rule is final agency action.

523. The rule is a legislative or substantive rule.

524. The rule is "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

525. No statute precludes judicial review of the rule, and the rule is not committed to agency discretion by law, under 5 U.S.C. § 701(a).

526. Plaintiffs have no adequate or available administrative remedy.

527. In the alternative, any effort to obtain an administrative remedy would be futile.

528. The rule is definitive and determines the rights and obligations of persons, including Plaintiffs.

529. HHS declares the rule will be treated as if it has the full force of law.

530. Plaintiffs face imminent, irreparable harm and are susceptible to risk of enforcement under the rule beginning on its effective date.

531. Plaintiffs' compliance costs constitute irreparable harm.

532. Absent injunctive and declaratory relief, ACPeds members have been and will continue to be harmed by continued exposure to legal penalties for practicing medicine in line with its best judgment and for speaking those views to its patients.

533. Unless the Court provides protection from Defendants' enforcement of the rule, Plaintiffs will continue to suffer from this ongoing violation of law.

534. Plaintiffs have no adequate remedy at law.

535. All the acts of Defendants described above, and their officers, agents, employees, and servants, were executed and are continuing to be executed by Defendants under the color and pretense of the policies, statutes, ordinances, regulations, customs, and usages of the United States.

536. The public interest would be served by judicial relief.

537. The rule would ultimately subject some of the States' most vulnerable citizens to a gender-transition protocol that will leave them with irreversible side effects— including sterilization—and increased health risks for the rest of their lives.

FIRST CLAIM
ADMINISTRATIVE PROCEDURE ACT
(5 U.S.C. § 706)

538. Plaintiffs reallege and incorporate herein, as though fully set forth, paragraphs 1–537 of this Complaint.

539. Plaintiffs bring this claim as to the rule's gender-identity nondiscrimination requirement and the implications thereof under the rule.

A. Not in Accordance with Law, In Excess of Statutory Jurisdiction, Authority, and Limitations, and Contrary to Right, Power, Privilege, and Immunity

540. Under the APA, a court must "hold unlawful and set aside agency action" if the agency action is "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "contrary to constitutional right, power, privilege, or immunity" under 5 U.S.C. § 706(2)(A)–(C).

541. The rule is not in accordance with law, is in excess of statutory jurisdiction, authority, and limitations, and is contrary to constitutional rights and power.

542. Congress has not delegated to the Defendants the authority to prohibit gender-identity discrimination under Section 1557.

543. The rule exceeds the authority of Section 1557, the Affordable Care Act, Title IX of the Education Amendments of 1972, and Section 504 of the Rehabilitation Act, as amended, as it constrains the sex-discrimination prohibition in the ACA.

544. The rule exceeds HHS's statutory authority because it defines discrimination "on the basis of sex" in a manner contrary to Section 1557 and Title IX.

545. The texts of Section 1557, the ACA, Title IX, and Section 504 as applicable to Section 1557, speak of sex as a biological binary that precludes imposing Section 1557 as if it prohibits gender-identity discrimination.

546. A covered entity's refusal to provide transition procedures discriminates instead based on clinical purpose, not a patient's sex, and based on medical necessity, not patient desire.

547. The rule's interpretation of these laws violates the major questions doctrine and the clear-statement federalism and spending clause canons.

548. Prohibiting discrimination on the basis of gender identity throughout the nation's health system, as a condition on receipt of federal health funding from HHS, is an issue of vast economic and political significance for which Congress did not give HHS clear authority.

549. The rule is contrary to Section 1554 of the ACA, 42 U.S.C. § 18114; specifically: parts (1)–(2) and (6) because it pressures healthcare providers like Plaintiffs out of federally funded health programs and the practice of healthcare; parts (3)–(4) because it requires healthcare providers like Plaintiffs to speak in affirmance of gender transition and to refrain from speaking in accordance with a patient's sex and related medical needs; and part (5) because it requires healthcare providers like Plaintiffs to deprive patients of informed consent by preventing them from warning patients of the dangers of transition procedures.

550. The rule is contrary to 42 U.S.C. § 18122(1), (2)(A), (3) because it seeks to establish the standard of care or duty of care owed by a health care provider to a patient and seeks to preempt State laws or common laws governing medical professional actions or claims.

551. HHS has no authority to impose disparate-impact liability under Section 1557.

552. HHS's justification for excluding the religious and education carveouts in Title IX, e.g., 87 Fed. Reg. at 37,532, is inconsistent with HHS's relying on the regulatory authorizations that are used to justify disparate impact regulations under Title VI (Section 602), *see, e.g., Gallagher v. Magner*, 636 F.3d 380, 383 (8th Cir. 2010) (Colloton, C.J., dissenting).

553. The rule's gender-identity mandate lacks authority under Section 504 of the Rehabilitation Act.

554. Section 1557 specifically excludes from its scope "transsexualism" and a "gender identity disorder" "not resulting from physical impairments." 42 U.S.C.

§ 18116(a) (prohibiting discrimination "on the ground prohibited under … section 794 of title 29"); 29 U.S.C. § 705(20)(F)(i) (providing that "transsexualism" and "gender identity disorders not resulting from physical impairments" are not a "disability" under section 794). Those terms at the time were synonymous with having a transgender identity, so such persons that do not have a disorder of sex development—a physical impairment—do not have a "disability" and are excluded from Section 504 of the Rehabilitation Act.

555. The specific exclusion of transgender identity governs the general prohibitions of Section 1557, so the general term "based on sex" cannot be read to include discriminating based on transgender identity in Section 1557.

556. Having gender dysphoria, identifying as transgender, non-binary, or otherwise contrary to sex is not a physical impairment.

557. Having gender dysphoria, identifying as transgender, non-binary, or otherwise contrary to sex falls under the exclusion for gender identity disorders or the catchall exclusion category.

558. Having gender dysphoria, identifying as transgender, non-binary, or otherwise contrary to sex does not necessarily substantially limit a major bodily function and is not a disability covered under Section 504.

559. HHS has no authority to create and impose requirements that involve compliance costs for covered entities beyond the requirement not to discriminate on grounds prohibited by Section 1557, such as by requiring policy changes, training, duties for compliance coordinators, grievance procedures, notices of nondiscrimination, and record-keeping.

560. Like Title IX, Section 1557 requires intentional discrimination on the basis of sex: It prohibits different treatment based on intent, not facially neutral policies or practices that have "the effect of discriminating" on the basis of sex or gender identity.

561. The rule violates and exceeds the authority of Sections 1902(a)(4) and 2101(a) of the SSA, 42 U.S.C. §§ 1396a(a)(4)(A), 1397aa, because the rule's gender-identity mandate is not necessary for the proper and efficient operation of a state plan, is not in the best interest of beneficiaries, and will not enable states to provide child health assistance in an effective and efficient manner.

562. Section 1902(a) of the SSA, 42 U.S.C. § 1396a(a)(4)(A), which requires State plans to provide "such methods of administration … as are found by the Secretary to be necessary for the proper and efficient operation of the plan," does not grant rulemaking authority or authorize the rule's gender-identity mandate.

563. Non-discrimination rules are not "methods of administration." Requiring the use of pronouns that differ from the individual's biological sex does not advance the goal of "efficient" "administration" of the Medicaid program.

564. The rule violates and exceeds the authority of Section 1902(a)(19) of the Social Security Act because the rule's gender-identity mandate does not provide for necessary safeguards, does not reduce confusion, does not facilitate simplicity in administration of nondiscrimination requirements, and does not ensure the best interests of the beneficiaries are met across Medicaid delivery systems for all Medicaid beneficiaries.

565. HHS's interpretation of Section 1902 as providing carte blanche authority to impose requirements on State Medicaid plans is inconsistent with the statutory text and violates the "clear notice" requirements for Spending Clause legislation and the major questions doctrine.

566. Section 2101(a) of the SSA, 42 U.S.C. § 1397aa, does not grant rulemaking authority or authorize the rule's gender-identity mandate. HHS's interpretation of Section 2101(a) is inconsistent with the text and statutory context, as well as the "clear notice" required by the Spending Clause and the major questions doctrine.

567. Section 1102, 1894(f)(A), and 1934(f)(A) of the SSA, 42 U.S.C. §§ 1302, 1395eee(f), 1396u-4(f) are general grants of rulemaking authority and do not authorize the rule's gender-identity mandate. HHS's reading of these provisions to afford near limitless rulemaking authority is contrary to statutory text and context, as well as the "clear notice" required by the Spending Clause and the major question doctrine.

568. Far from giving HHS any authority, Section 1801 of the SSA, 42 U.S.C. § 1395, prohibits HHS supervision or control over the practice of medicine or the manner in which medical services are provided or over the administration or operation of any institution, agency, or person providing services.

569. Culturally competent services need not include the rule's gender-identity mandate.

570. For the reasons discussed below in Claims Two and Three, the rule violates constitutional protections for free speech, association, and assembly, as well as structural constitutional principles related to federalism and Congress' enumerated powers.

B. Arbitrary, Capricious, and an Abuse of Discretion

571. Under the APA, a reviewing Court must "hold unlawful and set aside agency action" if the agency action is "arbitrary," "capricious," or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

572. In drafting and promulgating the rule, HHS failed to undergo reasoned decision-making.

573. HHS arbitrarily concluded that sex includes gender identity.

574. HHS arbitrarily based its rule on *Bostock* despite that decision's explicit disavowal of its application to other statutes or circumstances.

575. HHS failed to adequately consider and find that, in medical practice as in education, sex is a biological reality.

576. The rule never defines "sex." Without considering the definition of sex, HHS cannot reasonably explain what it means to discriminate "on the basis of" sex.

577. The rule failed to offer a "reasoned explanation" of the rule's departures from the agency's earlier factual findings and from Title IX's historic understanding of sex. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). HHS failed to demonstrate awareness that it was changing positions and failed to identify any facts or evidence that HHS had not considered (or that had changed) since 2020 and 2021. HHS doesn't explain why the evidence on gender transitions is no longer weak.

578. The rule was not supported by (and runs counter to) the evidence before HHS. HHS failed to adequately consider important aspects of these issues and all the evidence before the agency.

579. HHS failed to adequately consider the harm that comes to patients when covered entities ignore or misconstrue the biological differences between the sexes as demanded by the rule.

580. HHS entirely failed to consider the numerous negative side effects associated with transition procedures. HHS never acknowledged, for example, that its preferred "standard of care" may render an untold number of minors and adults infertile for the rest of their lives.

581. HHS failed to adequately consider that there is an evolving state of medical knowledge about "gender-transition" efforts and that the rule short-circuits this debate.

582. HHS improperly relied on unreliable facts and studies only from one side of the issue and improperly ignored or disregarded experts who point out that there is not enough evidence to require the provision of "gender transitions."

583. HHS failed to adequately consider that the proposed rule rested on evidence (such as the WPATH and Endocrine Society Guidelines) that comments showed had scientific weaknesses, that suffered from conflicts of interest, and that had been significantly undermined by the time of the final rule.

584. HHS arbitrarily concluded that the rule is necessary for the proper and efficient operation of a state plan, is in the best interest of beneficiaries, and will enable states to provide child health assistance in an effective and efficient manner.

585. HHS arbitrarily concluded that the rule provides for necessary safeguards, reduces confusion, will facilitate simplicity in administration of nondiscrimination requirements, and will ensure the best interests of the beneficiaries are met across Medicaid delivery systems for all Medicaid beneficiaries.

586. HHS arbitrarily concluded that culturally competent services must include the rule's provisions, including its pronoun mandate.

587. CMS relied on factors that Congress never intended it to consider. Congress authorized regulations to improve the efficiency of Medicaid and CHIP administration. Congress did not intend CMS to require "pursuing health equity"—*i.e.*, gender ideology.

588. HHS failed to adequately consider the disproportionately negative impact of the "gender-transition" mandate on women and girls.

589. HHS improperly ignored the effect of the rule on clinics that have medical and ethical objections to "gender-transition" procedures.

590. HHS improperly ignored the reliance interests of doctors and insurance providers on the absence of a "gender-transition" mandate under Section 1557.

591. HHS improperly ignored the reliance interests of patients who want to keep receiving care from clinics that object to "gender transitions."

592. HHS improperly failed to consider States' reliance interests in the status quo in the absence of a gender-identity mandate, including in their continued federal HHS funding and in the continued enforcement of their laws restricting gender-transition procedures.

593. HHS failed to adequately consider or quantify how the rule will drive thousands of healthcare providers out of medicine and harm underserved populations treated by those doctors.

594. HHS failed to adequately consider alternative policies.

595. HHS adopted the rule for reasons unrelated to the correct interpretation of Section 1557 or the best understanding of the scientific evidence. The rule cannot be adequately explained in terms of the correct interpretation of Section 1557 or the best understanding of the scientific evidence.

596. Defendants had made up their minds to adopt the rule well before the beginning or end of the APA's required decision-making process. The explanation for agency action is incongruent with what the record reveals about the agency's priorities and decision making process.

597. HHS's unfounded and shifting claims of legal authority appear to be a pretext (1) to avoid the limits on its own enforcement powers, (2) to promote HHS's own policy goals of imposing a sweeping gender-identity mandate on healthcare, and (3) to target with hostility child-protection laws, views, and advocates with which HHS disagrees.

598. The rule's rationale seems contrived for the President's policy convenience, political considerations, and other motives, and the rule therefore is inconsistent with *Department of Commerce v. New York*, 588 U.S. 752, 780–86 (2019).

SECOND CLAIM
STRUCTURAL PRINCIPLES OF FEDERALISM AND LACK OF ENUMERATED POWERS

599. Plaintiffs reallege and incorporate herein, as though fully set forth, paragraphs 1–598 of this Complaint.

600. Plaintiffs bring this claim as to the rule's gender-identity nondiscrimination requirement and the implications thereof under the rule.

601. The Constitution and federal rules authorize claims seeking to enjoin and declare unlawful federal agency actions that are *ultra vires* for violating constitutional authority, and the APA authorizes the Court to enjoin, hold unlawful, and set aside agency actions that are contrary to constitutional power or privilege or otherwise not in accordance with constitutional law.

602. Even if the rule's reinterpretation of Section 1557 and Title IX were a permissible interpretation of the statutes, it would be constitutionally impermissible.

603. The rule exceeds Congress's Article I enumerated powers and transgresses on the reserved powers of the States under the federal constitution's structural principles of federalism and the Tenth Amendment. U.S. Const. art. I, § 8, cl. 1; *id*. amend. X.

A. Lack of constitutionally required notice

604. For a statute to preempt the historic police powers of the States, to abrogate state sovereign immunity, or to regulate a matter in areas of traditional state responsibility, the Constitution limits the States' and the public's obligations to those requirements unambiguously set out on the face of the statute. *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981).

605. No funding recipient could unmistakably know or clearly understand that Section 1557, Title IX, Section 504, or the Social Security Act would impose

the mandate created by the rule as a condition of accepting federal funds from HHS.

606. The States could not have foreseen that Section 1557, Title IX, Section 504, or the Social Security Act would be wielded in such a way when they accepted these federal dollars from HHS and built extensive health programs—with annual budgets in the billions—in reliance on that funding.

607. The public lacked the constitutionally required clear notice that the statutes would apply in this way when Section 1557, Title IX, Section 504, or the Social Security Act were passed or when funding grants were made. *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

608. The rule unconstitutionally subjects States to private suits by employees and patients for failing to follow these gender-identity mandates without a clear statement waiving the States' sovereign immunity.

609. As the Fifth Circuit has held, the "needed clarity" to satisfy the Spending Clause "cannot be … provided" by "regulations clarifying an ambiguous statute." *Tex. Educ. Agency v. U.S. Dep't of Educ.*, 992 F.3d 350, 361 (5th Cir. 2021). Instead, it "must come directly from the statute." *Id.*

B. Exceeding the authority of spending power

610. The rule improperly goes beyond the authority Congress gave to HHS, or that Congress possesses and exercises in Section 1557.

611. Defendants expressly and impliedly, but improperly, seek to use a Spending Clause statute to preempt traditional state authority over healthcare, the healing professions, and standards of care.

612. The rule purports to override state conscience-protection laws as well as state laws restricting "gender-transition" procedures.

613. The rule requires the States and MCC to violate state laws and their core convictions as a condition of federal funding.

614. These state laws protect MCC's ability to operate without needing to provide, promote, facilitate, or speak in favor of such procedures.

615. Congress does not have the authority under the Spending Clause to preempt state law. An agency may not pay anyone to violate state law. Instead, if state law prevents the spending of federal funds in a certain way, the only thing an agency may do is disallow funds.

616. In addition, the ACA contains an express savings clause, confirming no broad "obstacle" preemption applies. *See* 42 U.S.C. § 18041(d) ("Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.").

C. Unconstitutional coercion

617. The rule requires the States and covered entities to follow the rule's gender-identity mandate as a condition of receiving federal healthcare funding. Federal Medicaid funding alone is about 27% of the average state budget, and any ineligibility for Medicare, Medicaid, or CHIP funding threatens to drive healthcare providers out of the practice of medicine entirely.

618. Such a requirement is unconstitutionally coercive. The rule requires the States and covered entities to adopt a controversial gender-identity mandate or give up more than 27% of state budgets and disregard the healthcare systems put in place over several decades. That leaves the States and covered entities with no meaningful choice. It is an improper use of the Spending Clause.

619. The States and Plaintiffs cannot accept the rule's gender-identity mandate because that would conflict with state restrictions on gender-transition procedures and state conscience-protection law. The federal government cannot

commandeer state governments in that way or require the States to repeal their laws. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 470–75 (2018).

620. Coercing the States and healthcare providers to abandon their laws or to give up federal healthcare funding that their federal tax dollars underwrite —which is what they must do to comply with the rule—is beyond the federal government's spending clause power. It amounts to a "gun to the head" for the States and covered entities. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012) (plurality). It is "economic dragooning that leaves the States with no real option but to acquiesce." *Id*. at 582 (plurality).

D. Lack of enumerated or delegated power

621. Defendants lack any authority to preempt state laws in these fields or to impose these conditions through any federal power.

622. HHS exceeds its authority because the rule pervasively regulates the practice of medicine and imposes a national standard of care for gender dysphoria—a matter within the traditional authority of the States and which Congress has not authorized the agency to regulate.

623. The rule transgresses "the Constitution's rule vesting federal legislative power in Congress," not agencies acting by "pen-and-phone regulations." *West Virginia v. EPA*, 597 U.S. 737, 737–38, 753 (Gorsuch, J., concurring). Reading "sex" as a term capacious enough to encompass a controversial gender-identity mandate, among other novel ideas, would shift "unfettered" lawmaking power to the Department in a manner the nondelegation doctrine does not tolerate. *See Tiger Lily, LLC v. U. S. Dep't of Hous. & Urban Dev.*, 5 F.4th 666, 672 (6th Cir. 2021).

624. To the extent that HHS predicates its new regulations on the "medical necessity standards" and "guidelines" issued by WPATH and the Endocrine

Society, they violate the private nondelegation doctrine. *See Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936). Handing off regulatory authority to private parties is "legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business"—or the public welfare. *Id.*; *see also Dep't of Transp. v. Ass'n of Am. Railroads*, 575 U.S. 43, 60–64 (2015) (Alito, J., concurring).

625. The rule cannot constitutionally subject States to private suits for money damages.

THIRD CLAIM
FREEDOM OF SPEECH AND ASSOCIATION
(FIRST AND FIFTH AMENDMENTS)

626. Plaintiffs reallege and incorporate herein, as though fully set forth, paragraphs 1–625 of this Complaint.

627. Plaintiffs bring this claim as to the rule's gender-identity nondiscrimination requirement and the implications thereof under the rule.

628. The Constitution and federal rules authorize claims seeking to enjoin and declare unlawful federal agency actions that are *ultra vires* for violating constitutional authority, and the APA authorizes the Court to enjoin, hold unlawful, and set aside agency actions that are contrary to constitutional power or privilege or otherwise not in accordance with constitutional law.

629. Under the First Amendment to the U.S. Constitution, "Congress shall make no law … abridging the freedom of speech … or the right of the people peaceably to assemble …." U.S. Const. amend. I.

630. Under the Fifth Amendment to the U.S. Constitution, "No person shall be … deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

631. ACPeds members' speech and practice in the context of healthcare is protected under the First Amendment.

632. The rule restricts and compels ACPeds members' speech in violation of the First Amendment.

633. The rule regulates speech based on content and viewpoint by requiring messages, information, referrals, and pronouns affirming transition efforts, and by prohibiting and restricting speech taking a contrary view.

634. ACPeds members seek to keep following their best medical and ethical judgments in communicating to patients, but the rule does not allow this.

635. But for the rule, ACPeds members would continue to speak freely on these matters in each clinical situation as they deem appropriate, as they have done until this mandate.

636. The rule violates ACPeds members' right of expressive association (or freedom of assembly) by coercing them to participate in facilities, programs, groups, and other healthcare-related endeavors that are contrary to its views and that express messages with which they disagree.

637. The rule's regulations impacting speech and association are not justified by a compelling interest and are not narrowly tailored to achieve the government's purported interests.

638. No relevant statute provides any governmental interest to sustain the speech regulations of the gender-identity mandate.

639. The rule is an overbroad restriction on speech, and it sweeps within its ambit a substantial amount of First-Amendment-protected speech and expression.

640. This overbreadth chills the speech of healthcare entities that engage in private speech through statements, notices, and other means in healthcare on the basis of sex.

641. The rule imposes an unconstitutional condition on ACPeds members' receipt of federal funding.

642. Defendants' implementation of the rule through instruments such as HHS's Form 690 requirement to assure compliance with Section 1557, or statements required to be made in award applications, notices of awards, or applications to qualify as providers in Medicaid, Medicare, or CHIP, function in a way that compels speech and requires self-censorship on condition of losing federal funds in violation of the First Amendment.

643. The nondiscrimination mandate is void for vagueness and gives officials' unbridled discretion in violation of due process rights.

644. The rule coerces ACPeds members' speech by forcing them to provide notices to patients that they do not discriminate on the basis of "gender identity."

645. ACPeds members hold views against providing, referring for, or affirming the legitimacy of "gender transition," and communicates those views to patients and the public.

646. By forcing ACPeds members to tell patients directly, on their walls, and on their websites that they do not discriminate on the basis of gender identity, the rule forces ACPeds members to speak falsely, and it forces ACPeds members to fatally undermine their communication of their own medical ethical standards. This undermines ACPeds members' reputation and brand as a trustworthy pediatrics clinic that follows state laws on "gender transitions."

647. The rule's coerced notices of nondiscrimination on gender identity fail any applicable level of scrutiny under the Free Speech Clause.

648. In the alternative, if Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, and to the extent Defendants enforce it as doing so, these statutes violate the First and Fifth Amendments of the U.S.

Constitution as applied to ACPeds members' and all similarly situated healthcare professionals.

FOURTH CLAIM
Relief Under the Declaratory Judgment Act, 28 U.S.C. § 2201; 5 U.S.C. § 706.

649. Plaintiffs reallege and incorporate herein, as though fully set forth, paragraphs 1–648 of this Complaint.

650. The Declaratory Judgment Act provides that in the case of an "actual controversy within its jurisdiction … any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

651. This case presents an actual controversy. The rule governs Plaintiffs, meaning its requirements affect their legal rights. Moreover, the imminent enforcement of the rule threatens to force recipients of federal HHS funding to choose between violating state law and abandoning consistent policies or losing their federal funding.

652. The controversy arises in this Court's jurisdiction, as it relates to questions of federal law. Venue is proper, as the State of Missouri resides in this District. 28 U.S.C. § 1391(e).

653. As set forth throughout this Complaint, Plaintiffs have filed an appropriate pleading to have their rights declared. The Court can resolve this controversy by declaring that the rule is unlawful, vacating it, and declaring that Plaintiffs, their political subdivisions, and their resident healthcare providers may continue receiving federal financial assistance notwithstanding any failure to adhere to the rule's unlawful requirements; that Section 1557 of the ACA (as well as Title IX of the Education Amendments of 1972 and Section 504 of the Rehabilitation Act as incorporated therein) or the Social Security Act, do not

prohibit discrimination on the basis of gender identity under the ACA; that the rule and Defendants' enforcement or defenses thereof violate or exceed the Administrative Procedure Act; 42 U.S.C. § 18023, 42 U.S.C. § 18114, the Social Security Act, 42 U.S.C. §§ 1302, 1395, 1395eee(f), 1396a(a)(4), 1396u-4(f), 1397aa; the Free Speech and Assembly Clauses of the First Amendment, the Fifth Amendment, the Tenth Amendment, the constitutional principles of federalism, the Spending Clause, HHS's delegated powers, and Congress's enumerated powers.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for judgment as follows and request the following relief:

A. That this Court declare unlawful, set aside, and vacate the rule to the extent it prohibits discrimination on the basis of gender identity;

B. That this Court issue a preliminary and permanent injunction and stay against Defendants implementing, enforcing, or applying a gender-identity nondiscrimination mandate under any aspect of the rule or Section 1557 of the ACA (as well as Title IX of the Education Amendments of 1972 and Section 504 of the Rehabilitation Act as incorporated therein) or the Social Security Act, including that Defendants may not require covered entities to:

1. Perform, provide, offer, refer for, facilitate, make arrangements for, endorse, or refrain from criticizing or from categorically rejecting "gender transition";

2. Allow members of one sex into the private spaces or sex-specific programs of the other sex in their facilities, such as by allowing males into female restrooms, lactation rooms, or exam rooms;

3. Speak in ways that the entities contend inaccurately refers to a patient's sex, such as in pronoun usage, coding, charting, or conversation, or be forced to say that a boy is a girl or vice versa, or say that men can get pregnant, give birth, or breastfeed;

4. Stay silent on the negative impacts of "gender-transition" efforts, including by being unable to say that they do not provide, offer, refer for, or endorse those procedures, or by being pressured to withhold criticism or their complete opinions on these subjects, or by being unable to use accurate sex-specific language in speech or writing;

5. Affirm "gender-transition" efforts, or refrain from providing criticism or their full opinions to patients on these subjects; or

6. Make statements in their policies, notices, or website statements, or train staff, or speak to patients or visitors, or submit assurances or certifications of compliance, to the effect that the entity will not discriminate on the basis of gender identity, or of any nondiscrimination category in the rule or Section 1557 to the extent that Defendants contend it encompasses gender-identity nondiscrimination.

C. That under Article I and the Tenth Amendment, this Court preliminarily and permanently enjoin Defendants from implementing,

enforcing, or applying the rule, or Section 1557 of the ACA, to the extent it prohibits discrimination on the basis of gender identity.

D. That under the First and Fifth Amendments, this Court preliminarily and permanently enjoin Defendants from implementing, enforcing, or applying the rule, or Section 1557 of the ACA (as well as Title IX of the Education Amendments of 1972 and Section 504 of the Rehabilitation Act as incorporated therein) or the Social Security Act, in any aspect of a covered entity's expression to the extent it prohibits discrimination on the basis of gender identity, including as described in *supra* Prayer for Relief B.3–6, including but not limited to the requirement that Plaintiffs provide notices to patients that they do not discriminate on the basis of gender identity.

E. That under 5 U.S.C. § 705 this Court enjoin and declare the rule unenforceable on a preliminary basis and delay or stay its effective date to preserve status and rights pending review of this Court to the extent it prohibits discrimination on the basis of gender identity;

F. That this Court render declaratory judgment that Section 1557 of the ACA (as well as Title IX of the Education Amendments of 1972 and Section 504 of the Rehabilitation Act as incorporated therein) and the Social Security Act, do not prohibit discrimination on the basis of gender identity under the ACA;

G. That this Court render declaratory judgment that Plaintiffs, their political subdivisions, and their resident healthcare providers may continue receiving federal financial assistance notwithstanding any failure to adhere to the rule's unlawful requirements;

H. That this Court render declaratory judgment that the rule and Defendants' enforcement or defenses thereof to the extent prohibiting discrimination on the basis of gender identity violate or exceed the Administrative Procedure Act; 42 U.S.C. § 18023; 42 U.S.C. § 18114; the Social Security Act, 42 U.S.C. §§ 1302, 1395, 1395eee(f), 1396a(a)(4), 1396u-4(f), 1397aa; the Free Speech and Assembly Clauses of the First Amendment; the Fifth Amendment; the Tenth Amendment; the constitutional principles of federalism; the Spending Clause; HHS's delegated powers; and Congress's enumerated powers;

I. That this Court extend such relief to run against Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office; including any actions to deny federal financial assistance or qualification for participation in federally funded programs or activities because of the failure to perform, offer, endorse, proscribe, or refer for either gender-transition efforts, or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions;

J. That this Court expressly extend all such relief to protect and benefit any of Plaintiffs' current or future operations, employees, or persons acting in concert or participation with Plaintiffs as necessary to protect Plaintiffs' functions;

K. That this Court define such relief to encompass any language or alternative theory in the rule that Defendants may use to achieve those same ends as to gender identity, such as sex stereotypes, disability, or disparate-impact liability;

L. That this Court adjudge, decree, and declare the rights and other legal relations of the parties to the subject matter here in controversy so that such declarations will have the force and effect of final judgment;

M. That this Court retain jurisdiction of this matter to enforce this Court's orders;

N. That this Court grant to Plaintiffs reasonable costs and expenses of this action, including attorneys' fees in accordance with any applicable federal statute, including 28 U.S.C. § 2412.

O. That this Court grant the requested injunctive relief without a condition of bond or other security being required of Plaintiffs; and

P. That this Court grant all other just and proper relief.

Respectfully submitted this 10th day of July, 2024.

/s/ Maria A. Lanahan

ANDREW BAILEY
Missouri Attorney General

Maria A. Lanahan, 65956(MO)
Deputy Solicitor General of Missouri
Office of the Missouri Attorney General
815 Olive Street, Suite 200
St. Louis, Missouri 63101
Telephone: (314) 340-4978
Facsimile: (573) 751-0774
Maria.Lanahan@ago.mo.gov

Counsel for Plaintiff State of Missouri

Julie Marie Blake
97891(VA), 69643(MO)
Alliance Defending Freedom
44180 Riverside Parkway
Lansdowne, Virginia 20176
Telephone: (571) 707-4655
Facsimile: (571) 707-4790
jblake@ADFlegal.org

Matthew S. Bowman
993261(DC)
Alliance Defending Freedom
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690
Facsimile: (202) 347-3622
mbowman@ADFlegal.org

Counsel for Plaintiff American College of Pediatricians

SEAN D. REYES
Utah Attorney General

Joseph Scott St. John 36682(LA)*[117]
Special Assistant Solicitor General
ST. JOHN LLC
1701 Jefferson Avenue
New Orleans, LA 70115
Telephone: 410-212-3475
scott@stjohnlaw.com

Counsel for Plaintiff State of Utah

TIM GRIFFIN
Arkansas Attorney General

Nicholas J. Bronni, AR2016167(AR)
Solicitor General of Arkansas
Dylan L. Jacobs, AR2016097(AR)
Deputy Solicitor General
Office of the Arkansas Attorney General
323 Center Street, Suite 200
Little Rock, AR 72201
Telephone: (501) 682-2007
Nicholas.bronni@arkansasag.gov
Dylan.jacobs@arkansasag.gov

Counsel for Plaintiff State of Arkansas

[117] Attorneys with an asterisk are not yet admitted to the E.D. Mo.

BRENNA BIRD
Iowa Attorney General

Eric H. Wessan, 154497(IA)
Solicitor General
1305 E. Walnut Street
Des Moines, Iowa 50319
(515) 823-9117
(515) 281-4209 (fax)
eric.wessan@ag.iowa.gov

Counsel for Plaintiff State of Iowa

DREW H. WRIGLEY
North Dakota Attorney General

Philip Axt, 09585(ND)
Solicitor General
North Dakota Attorney General's Office
600 E. Boulevard Ave., Dept. 125
Bismark, ND 58505
(701) 328-2210
pjaxt@nd.gov

Counsel for Plaintiff State of North Dakota

MARTY JACKLEY
South Dakota Attorney General

Clifton Katz, 2816(SD)*
Assistant Attorney General
Office of the South Dakota Attorney General
1302 E. Hwy 14
Suite 1
Pierre, SD 57501-8501
(605) 773-3215
Clifton.Katz@state.sd.us

Counsel for Plaintiff State of South Dakota

RAÚL R. LABRADOR
Idaho Attorney General

Joshua N. Turner, 12193(ID)*
Chief of Constitutional Litigation and Policy
Alan Hurst, 12425(ID)*
Solicitor General
Office of the Idaho Attorney General
P.O. Box 83720
Boise, ID 83720
(208) 334-2400
Josh.Turner@ag.idaho.gov
Alan.Hurst@ag.idaho.gov

Counsel for Plaintiff State of Idaho